

ALLIQUA BIOMEDICAL, INC.

Comments to the Advisory Panel on Hospital Outpatient Payment: Status Indicator for NLFU Therapy (CPT Code 97610)

In a divergence from longstanding policies and practices implemented by the Centers for Medicare & Medicaid Services (“CMS”), the 2016 Hospital Outpatient Prospective Payment System (“OPPS”) Final Rule (“2016 Final Rule”)¹ assigned a “Q1” status indicator to the procedure code describing non-contact low-frequency ultrasound therapy (“NLFU Therapy”). By assigning status indicator “Q1” to CPT code 97610, the 2016 Final Rule identifies NLFU Therapy as an “ancillary service” that is not separately payable when billed for the same patient on the same date of service as a “significant procedure” (*i.e.*, a procedure assigned status indicators “S,” “T,” or “V”). In contrast to this characterization, NLFU Therapy is in fact a significant, independent procedure—not an ancillary procedure. Alliqua Biomedical Inc. (“Alliqua”), the manufacturer of the MIST Therapy System, respectfully requests that the Advisory Panel recommend to CMS that it revert the status indicator assigned to CPT code 97610 back to status indicator “T,” rather than “Q1,” to accurately reflect NLFU Therapy’s independent nature and rectify a packaging policy error that threatens to limit beneficiary access to a proven wound-healing technology.

I. BACKGROUND

Prior to January 1, 2016, providers and practitioners performing NLFU Therapy were eligible to receive separate Medicare reimbursement for the procedure in the hospital outpatient setting because both codes used to describe NLFU Therapy—CPT code 0183T from 2009 to 2013, and code 97610 in 2014 and 2015—were assigned status indicator “T” for Medicare purposes. By assigning status indicator “T” to NLFU Therapy, CMS indicated its conclusion that NLFU Therapy was a “major separately payable service under the OPPS.”² When code 0183T was replaced with new Category I CPT code 97610, effective January 1, 2014, CMS retained status indicator “T” for CPT code 97610, again indicating its conclusion that NLFU Therapy was a major separately payable procedure.³ In the 2015 OPPS Final Rule, CMS performed a comprehensive reassessment of the procedures it considered ancillary to primary services for purposes of packaging.⁴ In this review, CMS considered both the clinical and resource-use aspects of the procedures, evaluating whether services were “minor diagnostic

¹ See Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs 80 Fed. Reg. 70298, Addendum B (Nov. 13, 2015) (“2016 Final Rule”).

² See Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs 77 Fed. Reg. 68210, 68232 (Nov. 15, 2012) (“2013 Final Rule”) (describing “S” and “T” codes as “a major separately payable service under the OPPS”); 2013 Final Rule, at Addendum B.

³ See Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs 78 Fed. Reg. 74,826 Appendix B (Dec. 10, 2013) (“2014 Final Rule”).

⁴ See Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs 79 Fed. Reg. 66,770, 66819 (Nov. 10, 2014) (“2015 Final Rule”).

tests” or “procedures that are often performed with a primary service,” as well as whether the geometric mean cost (“GMC”) of procedures exceeded \$100. After performing this comprehensive assessment, CMS again concluded in the 2015 Final Rule that NLFU Therapy was a major separately payable procedure, retaining the “T” status indicator for code 97610. In the 2016 Final Rule, however, CMS unexpectedly reversed its position on packaging for this procedure, instead deeming NLFU Therapy an ancillary service.⁵ CMS did not indicate how its longstanding analysis of NLFU Therapy’s clinical and resource use aspects changed to inform the Agency’s decision to reach the opposite conclusion that it had reached in prior years.

II. CMS PACKAGING POLICY CRITERIA

Under the authority of Section 1833(t) of the Social Security Act, CMS promulgated regulations governing the prospective payment system for services furnished to Medicare beneficiaries by hospital outpatient departments,⁶ establishing bundled national payment rates for covered services that are intended to reimburse providers for all operating and capital-related costs that are “integral, ancillary, supportive, dependent, or adjunctive to performing a procedure or furnishing a service on an outpatient basis.”⁷ The costs of “ancillary services” may be packaged or conditionally packaged into the payment for the related procedure or service.⁸ CMS assigns “status indicators” to the HCPCS and CPT codes of items and procedures to identify whether they are paid under the OPPTS, and if so, whether payment is made separately, packaged, or conditionally packaged.⁹ CMS uses status indicator “Q1” to identify “STV-packaged services,” which are conditionally packaged codes that receive separate payment under the OPPTS only if there is no service with status indicators “S,” “T,” or “V” reported with the same date of service on the same claim.¹⁰

CMS has clarified in guidance that “packaged services are items and services that are considered to be an integral part of another service that is paid under the OPPTS.”¹¹ Since 2000, the OPPTS has packaged payment for items and services that are “typically integral, ancillary, supportive, dependent, or adjunctive to a primary service.”¹² CMS has often noted that it considers multiple factors when deciding whether to package a service, including “whether the service is normally provided separately or in conjunction with other services; how likely it is for the costs of the packaged code to be appropriately mapped to the separately payable codes with

⁵ See 2016 Final Rule, at Addendum B.

⁶ See 42 U.S.C. § 1395l; 42 C.F.R. § 419.1 *et seq.*

⁷ See 42 C.F.R. § 419.2(b).

⁸ See *id.*

⁹ See CMS, Medicare Claims Processing Manual, Ch. 4, § 10.1.1 (2015).

¹⁰ See *id.* § 10.4.

¹¹ See *id.*

¹² See 2016 Final Rule at 70344 (emphasis added) (“Because packaging encourages efficiency and is an essential component of a prospective payment system, packaging payment for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPTS since its implementation in August 2000.”).

which it was performed; and whether the expected cost of the service is relatively low.”¹³ CMS has also stated on numerous occasions that it relies upon HCPCS code descriptors and the descriptions of procedures provided by the American Medical Association (“AMA”) CPT codes to determine whether medical items and services are “primary” or “ancillary and supportive.”¹⁴

III. NLFU THERAPY IS AN INDEPENDENT, PRIMARY CLINICAL PROCEDURE

NLFU Therapy, as provided by the MIST Therapy System, utilizes a non-contact, low-energy ultrasound device to deliver continuous ultrasonic energy to atomize saline and deliver a continuous mist to the treatment site. The system utilizes procedure-specific equipment to effect a specifically desired clinical effect in certain acute and non-healing wounds to foster healing mechanisms and remove barriers to healing. Treatment with noncontact low-frequency ultrasound at 40 kHz has been demonstrated to improve wound healing by destroying bacterial cells, reducing pseudomonas biofilm, downregulating pro-inflammatory cytokines and metalloproteinases, and upregulating vascular endothelial growth factors and other angiogenic factors that contribute to improved microcirculation.¹⁵ MIST Therapy is the only non-contact ultrasound device cleared by the FDA with an indication to promote wound healing.

The necessary equipment to perform MIST Therapy includes an ultrasound generator, transducer, and applicator. The ultrasound generator delivers energy into the wand-like transducer, which converts the energy into vibrations that create low-frequency sound waves. The metal tip of the transducer vibrates over 40,000 times per second. The sound waves pass from the transducer to the applicator, which dispenses saline as a conduit for delivering the sound waves to the wound bed.

A provider begins a MIST Therapy treatment by positioning the patient for wound evaluation and treatment. The provider first performs a careful assessment, measurement, and photography of the wound before cleaning it and any surrounding tissue. Once the provider has determined the amount of saline necessary for the treatment session, he or she places the applicator onto the treatment wand, attaches a saline bag, primes the applicator, and closes the

¹³ See 76 Fed. Reg. 74122, 74184 (Nov. 31, 2011); 75 Fed. Reg. 72128, 71862 (Nov. 24, 2010); 74 Fed. Reg. 60316, 60409 (Nov. 20, 2009); 73 Fed. Reg. 68502, 68572 (Nov. 18, 2008); 72 Fed. Reg. 66664 (Nov. 27, 2007) (“2008 Final Rule”).

¹⁴ See, e.g., 2008 Final Rule.

¹⁵ See, e.g., Prather J. et al., *Prospective randomized controlled trial comparing the effects of noncontact low-frequency ultrasound with standard care in healing split-thickness donor sites*, 221 J. AM. COLL. OF SURGEONS 309 (Aug. 2015); Maan Z. et al., *Non-contact low frequency ultrasound therapy enhances neovascularization and wound healing in diabetic mice*, 134 PLASTIC RECONSTRUCTION SURGERY (Sept. 2014); Seth A. et al., *Noncontact, lowfrequency ultrasound as an effective therapy against Pseudomonas aeruginosa infected biofilm wounds*, 21 WOUND REPAIR & REGENERATION 266 (Mar. 2013); Driver V. et al., *Noncontact low-frequency ultrasound therapy in the treatment of chronic wounds: a metaanalysis*, 19 WOUND REPAIR & REGENERATION 475 (July 2011); Kavros, S., *Treatment of Ischemic Wounds with noncontact Low-Frequency Ultrasound: The Mayo Clinic Experience, 2004-2006*, 20 SKIN & WOUND CARE 221 (Apr. 2007); Kavros S. & Schenck E., *Use of noncontact low frequency ultrasound in the treatment of chronic foot and leg ulcerations: a 51-patient analysis*, 97 J. AM. PODIATRIC MED. ASS’N 95 (Mar. 2007); Ennis W. et al., *Ultrasound therapy for recalcitrant diabetic foot ulcers: results of a randomized, double-blind, controlled, multicenter study*, 51 OSTOMY WOUND MANAGEMENT 24 (Aug. 2005).

tubing clamp. Tubing is then inserted into the saline pump, the tubing clamp is opened, and treatment may begin.

MIST Therapy is applied by positioning the leading edge of the applicator 0.5 to 1.5 cm from the wound and pressing the trigger button on the transducer. Both the saline and ultrasound begin, and the timer on the transducer wand display begins to count down, indicating that ultrasound is being delivered. Treatment is delivered by slowly moving the transducer wand in a horizontal and vertical pattern over the wound bed. The applicator is moved in a serpentine fashion along the entire wound and wound margin. The provider will wipe the wound bed with gauze and assess the wound bed and surrounding tissue for clinical changes. The provider then applies appropriate dressings. The entire system is cleaned following each treatment using disinfectant wipes. A survey of MIST Therapy practitioners conducted by Alliqua BioMedical indicated that the average length of time to complete MIST Therapy treatment exceeds 20 minutes.

Published clinical data confirm that significant improvement can be achieved through the use of NLFU Therapy in the treatment of certain wounds. As a general matter, the benefits of NLFU Therapy can be divided into two categories: (1) removing barriers to healing; and (2) stimulating cells to promote healing. Both of these benefits can be broken down further into specific factors and different types of wounds, all of which have been shown to be impacted positively by NLFU Therapy:

1. Removal of Barriers to Healing
 - a. Reduces a wide-range of bacteria¹⁶
 - b. Disrupts biofilm¹⁷
 - c. Reduces sustained inflammation¹⁸
 - d. Reduces MMP-9¹⁹
2. Stimulates Cells to Promote Healing
 - a. Increased blood flow through vasodilation²⁰

¹⁶ See Serena T. et al., *The Impact of Noncontact, Nonthermal, Low-Frequency Ultrasound on Bacterial Counts in Experimental and Chronic Wounds*, 55 OSTOMY WOUND MANAGEMENT 22 (2009); Kavros, *51 Patient Analysis*, *supra* note 15; Kavros S. et al., *The Effect of Ultrasound Mist Transfer Technology on Virulent Bacterial Wound Pathogens*. Abstract, Presented at Symposium on Advanced Wound Care, 2002.

¹⁷ See Seth, *supra* note 15.

¹⁸ See Yao M. et al., *A Pilot Study Evaluating Noncontact Low Frequency Ultrasound and Underlying Molecular Mechanism on Diabetic Foot Ulcers*, 11 INT. WOUND J. 586 (Dec. 2014); Escandon J. et al., *A Prospective Pilot Study of Ultrasound Therapy Effectiveness in Refractory Venous Leg Ulcers*, 9 INT. WOUND J. 570 (2012).

¹⁹ See Yao, *supra* note 18.

- b. Increased angiogenesis²¹
- c. Early release of growth factors²²
- d. Increased collagen deposition²³

NLFU Therapy achieves these beneficial effects through multiple mechanisms, including cavitation, microstreaming, and the application of micromechanical stress.²⁴ Cavitation involves the production and vibration of micron-sized bubbles within tissue fluids. These vibrating micron-bubbles collect and condense in the tissue fluids, moving from area to area during NLFU treatment.²⁵ This “microstreaming” involves the movement of fluids along acoustical boundaries as a result of ultrasound, as well as the development of microscopic cavities created by the formation of micro-bubbles.²⁶ Cavitation and microstreaming create mechanical energy that is capable of altering cell membrane activity while stimulating signal-transduction pathways.²⁷ This stimulation has direct implications for wound healing, such as leukocyte adhesion; growth factor production; collagen production; and increases in angiogenesis, macrophase responsiveness, fibrinolysis, and nitric oxide.²⁸ Another critical benefit of NLFU Therapy is its ability to reduce bacteria within and below the wound bed through the application of micromechanical stress that fractures the cell walls / membranes of a wide range of bacteria (*e.g.*, MRSA, VRE, pseudomonas), causing cell death.

Importantly, while practitioners typically continue the use of standard wound care when treating wounds with NLFU Therapy, the improved clinical outcomes seen in patients treated with NLFU Therapy are the direct result of NLFU Therapy itself, independent of any other service that may be performed on the same date of service. For instance, NLFU Therapy and debridement are two independent therapeutic modalities with distinct clinical benefits that are neither “ancillary” nor “primary” to the other procedure. Debridement, described by CPT codes 11042-11047 and others, involves the removal of infected, contaminated, damaged, devitalized,

²⁰ See Liedl D. & Kavros S., *The Effect of Mist Ultra-sound Transport Technology on Cutaneous Microcirculatory Blood Flow*, Abstract, Presented at Symposium on Advanced Wound Care, 2001.

²¹ See Yao, *supra* note 18; Thawer, H. & Houghton, P., *Effects of Ultrasound Delivered Through a Mist of Saline to Wounds in Mice with Diabetes Mellitus*, 13 J. WOUND CARE. (2004); Maan Z. et al., *Evaluation of the Role on Noncontact Low-Frequency Ultrasound Therapy on Angiogenesis During Wound Healing*, Poster Presentation ACS (2013).

²² See Yao, *supra* note 18; Lai J. & Pittelkow M., *Physiological Effect of Ultrasound MIST on Fibroblasts*, 46 INT. J. DERMATOLOGY 587 (2007).

²³ See Thawer, *supra* note 21; Maan, *supra* note 21.

²⁴ See Kavros, *The Mayo Clinic Experience*, *supra* note 15 (citing Webster DF et al., *The role of cavitation in the in vitro stimulation of protein synthesis in human fibroblasts by ultrasound*, 4 ULTRASOUND MED. BIO. 343 (1978)).

²⁵ See Ennis, *supra* note 15.

²⁶ See *id.*

²⁷ See Kavros, *The Mayo Clinic Experience*, *supra* note 15 (citing Dinno M. et al., *The significance of membrane changes in the safe and effective use of therapeutic and diagnostic ultrasound*, 34 Physics Med. Bio. 1543 (Nov. 1989)).

²⁸ See, *e.g.*, Kavros, *The Mayo Clinic Experience*, *supra* note 15.

necrotic, or foreign tissue from a wound.²⁹ Providers typically use forceps, scalpels, scissors, or tissue nippers to facilitate sharp or blunt dissection, curettement, scrubbing, and/or forceful irrigation.³⁰ Debridement is intended to promote wound healing by removing sources of infection and other mechanical impediments.³¹

In contrast, NLFU Therapy does not function as an instrument that removes devitalized or infected tissue from a wound. While debridement is focused on removing unhealthy tissue from a wound, NLFU Therapy stimulates living tissue present in the wound to facilitate wound healing. The application of ultrasound waves also reduces the bacteria load, disrupts the formation of any biofilm, and reduces inflammation. In fact, a survey of NLFU Therapy practitioners found that they typically use MIST Therapy as the *only* therapeutic modality in the plan of care for deep tissue injuries, painful wounds, and ischemic wounds that are not ideal candidates for sharp or excisional debridement.

IV. CPT DESCRIPTORS AND CODING GUIDANCE CHARACTERIZE NLFU THERAPY AS A PRIMARY, INDEPENDENT SERVICE

Since the inception of the current OPPS packaging policy in 2008, CMS has relied upon HCPCS descriptors and the AMA’s CPT descriptors to determine whether medical items and services are “primary” or “ancillary and supportive” for purposes of packaging.³² Recognizing the fundamental role of HCPCS codes in describing services furnished, CMS concluded that “we look to the HCPCS definitions of the service to determine whether a particular service is ancillary and supportive of another service.”³³ In promulgating the 2016 Final Rule, in which NLFU Therapy was first deemed an “ancillary service,” CMS again acknowledged that the Agency “examined the HCPCS code definitions (including CPT code descriptors) to determine whether there were categories of codes for which packaging would be appropriate according to existing OPPS packaging policies or a logical expansion of those OPPS packaging policies.”³⁴

In contrast to CMS’s 2016 packaging determination but consistent with CMS’s previous decisions from 2009 through 2015, the CPT descriptor of code 97610 identifies NLFU Therapy as a standalone, independent service. The code descriptor describes the procedure as “low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day.”³⁵ This descriptor specifies that the NLFU Therapy service includes wound assessment and the provision of separate patient instructions for ongoing care, in addition to the performance of NLFU Therapy itself. Because the CPT code 97610 by definition describes a standalone procedure for a

²⁹ See, e.g., National Government Services, Inc., *Local Coverage Determination (LCD): Debridement Services* (L33614).

³⁰ *Id.*

³¹ *Id.*

³² See, e.g., 2008 Final Rule, at 66620.

³³ See *id.*

³⁴ See 2016 Final Rule, at 70344.

³⁵ See American Medical Association, CPT CODEBOOK: PROFESSIONAL EDITION at 630 (2015 ed.).

particular modality of wound care, it inherently describes an independent service not ancillary to another “primary” procedure.

Beyond the code descriptor, additional coding guidance provided by the AMA also speaks to the independent nature of NLFU Therapy. In the June 2014 *CPT Assistant*, the AMA provided a comprehensive overview of the proper use of code 97610 to describe NLFU Therapy.³⁶ The AMA described the procedure as a standalone, independent service, specifying that a qualified health care professional must be in “continuous attendance” during the provision of NLFU Therapy. The clinical vignette included in the *CPT Assistant* illustrated that the service described by 97610 includes “careful wound assessment, measurement, and photography” before cleansing the wound and surrounding tissue, specifying that the code did not simply describe the application of ultrasound energy. At the conclusion of the procedure, the qualified health care professional must perform an additional assessment of the wound bed and surrounding tissue before applying the appropriate dressing. In sum, the AMA’s guidance describes 97610 as a standalone clinical procedure that need not be paired with another evaluation or treatment planning procedure code to describe the services already included within the 97610 procedure.

Critically, the AMA also indicated in its coding guidance from June 2014 that selective debridement and NLFU Therapy do not have an ancillary / primary procedure relationship. In fact, the AMA instructed that NLFU Therapy and selective debridement “represent different interventions using different medical equipment with distinctly different clinical outcomes.”³⁷ As discussed in further detail below, by assigning status indicator “Q1” to NLFU Therapy, in more than 33% of claims where NLFU is packaged with another procedure, the service would be packaged with a debridement procedure (based on CMS’s 2014 claims analysis). This result would conflict directly with AMA coding guidance, upon which CMS continues to rely to support the Agency’s packaging policy determinations.

V. CLAIMS DATA SUPPORTS THE INDEPENDENT NATURE OF CODE 97610

In addition to examining code descriptors and coding guidance, in the 2014 Final OPPTS Rule, CMS described the Agency’s ancillary services packaging policy as one that would package payment for “minor diagnostic tests and procedures that are typically performed with a primary service.”³⁸ While CMS did not finalize the ancillary service packaging policy in 2014,³⁹ in the 2015 OPPTS Final Rule, the Agency implemented the packaging policy while repeating its intent to make the OPPTS “more of a prospective payment system with expanded packaging of items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service.”⁴⁰ In contrast to the parameters and intent of the OPPTS packaging policy, a review of Medicare outpatient claims data confirms that NLFU Therapy is typically performed as an independent procedure and not, in fact, typically performed with a primary service.

³⁶ See American Medical Association, *Medicine: Active Wound-Care Management: Low-Frequency Ultrasound*, CPT ASSISTANT ONLINE 11 (June 2014).

³⁷ See *id.*

³⁸ See 2014 Final Rule, at 74945 (emphasis added).

³⁹ See *id.*, at 74946.

⁴⁰ See 2015 Final Rule, at 66819 (emphasis added).

A review of 2014 CMS claims data performed by Braid-Forbes Health Research LLC concluded that NLFU Therapy is most often performed as a standalone procedure. Moreover, in those instances when NLFU Therapy and another service are performed on the same patient on the same date of service, those services would not appropriately be considered as “primary” to the NLFU Therapy. According to this analysis of the claims data published with the proposed 2016 OPPS rule, there were a total of 12,091 claim lines with CPT code 97610, with approximately 5,500 of those claims representing single claims (*i.e.*, no other procedure billed). There were 5,031 NLFU Therapy procedures billed with other services on the same day and packaged into those other procedure codes. None of these other procedures, however, is appropriately characterized as being a “primary” procedure in relation to NLFU Therapy. For instance, 36% of the packaged claim lines (1,825 of 5,031) were billed with debridement services described by CPT codes 97597 or 11042. As described above, the AMA specifically instructed that debridement and NLFU Therapy “represent different interventions using different medical equipment with distinctly different clinical outcomes,” negating any suggestion that NLFU Therapy should be considered to be ancillary to debridement. Another 15% of the packaged claim lines (738 of 5,031) were related to CPT code 29581, which describes the application of a multi-layer compression system. These interventions have markedly different clinical purposes, are performed through separate procedures, and have no overlap of equipment used to perform NLFU Therapy and apply a multi-layer compression system.

Finally, 41% of the packaged claim lines (2,046 out of 5,031) relate to NLFU Therapy services billed with HCPCS code G0463, the code adopted to replace the former evaluation and management codes, which is described as a “hospital outpatient clinic visit for assessment and management of a patient.” Once again, the CPT code descriptor for NLFU Therapy identifies it as an independent, separate service from the general assessment and management of the patient. The AMA states that the procedure described by code 97610 already includes “wound assessment” consisting of wound measurement and photography, before cleansing the wound and surrounding tissue; “instruction(s) for ongoing care” to educate the patient; and, at the conclusion of the procedure, an additional assessment of the wound bed and surrounding tissue before applying the appropriate dressing. This list of services demonstrates that 97610 is truly a standalone, independent procedure that is not ancillary or supportive of a typical hospital outpatient visit for general patient assessment and management.

Due to the clear instructions in the NLFU Therapy CPT code and related AMA coding guidance, none of the four most common codes with which NLFU Therapy was billed in 2014—making up 92% of the packaged claim lines—could be characterized as related or “primary” to NLFU Therapy. As such, there is no support in the 2014 claims data that NLFU Therapy is typically provided as an ancillary service that should be packaged into payment for a primary service.

VI. NLFU THERAPY COST DATA WEIGH AGAINST PACKAGING

In prior OPPS publications, CMS has also acknowledged the role of procedure costs in determining whether to package a service, stating that CMS has “historically considered a variety

of factors, including . . . whether the expected cost of the service is relatively low.”⁴¹ Consistent with this principle, in the 2015 Final Rule, CMS limited the initial set of APCs with conditionally packaged services to those APCs with a geometric mean cost of less than or equal to \$100.⁴² CMS adopted this cost threshold for establishing packaged ancillary service APCs in response to public comments expressing concern that some relatively costly ancillary services could have otherwise been packaged into high volume but relatively inexpensive primary services.⁴³ At the time of this determination, NLFU Therapy was assigned to former APC 0015, which had a calculated GMC that exceeded the \$100 ceiling (\$151.59).⁴⁴ Although CMS reconfigured the debridement and skin procedures APC categories in 2016, the new APC 5051 continues to exceed the \$100 GMC threshold, with a GMC of \$123.29.⁴⁵ Consistent with its existing packaging policy, CMS should recognize that this GMC weighs against conditional packaging of procedures within APC 5051, including NLFU Therapy, when the procedures are not otherwise ancillary to a primary treatment or diagnostic procedure.

In fact, an examination of the procedures assigned to APC 5051 suggests that CMS made just this determination, but simply came to the wrong conclusion for NLFU Therapy. Unlike other APCs in which all assigned procedure codes are either conditionally packaged or not, APC 5051 contains HCPCS codes assigned a variety of status indicators, including indicators designating both primary and conditionally packaged procedures.⁴⁶ This mix of status indicators demonstrates that CMS has already exercised its discretion to designate procedures within APC 5051 as primary procedures, and based on the information presented above, CMS should do the same with CPT code 97610.

CONCLUSION

CMS considers a variety of factors to determine whether a procedure should be considered ancillary to a primary service, including the cost of the procedure, whether it is typically performed with a primary service, and whether it is an independent service or supportive or otherwise adjunctive to another service. A close examination of clinical effects, coding guidance, claims data, and cost data related to NLFU Therapy demonstrates that under each consideration, NLFU Therapy is more appropriately characterized as an independent, primary procedure than a supportive, ancillary procedure. CMS itself came to this same conclusion for five years, when NLFU Therapy was described by code 0183T from 2009 to 2013 and code 97610 in years 2014 and 2015. In light of this information, Alliqua respectfully requests that the Advisory Panel recommend that CPT code 97610 be reassigned its prior status indicator, “T,” instead of the “Q1” status indicator.

⁴¹ See 76 Fed. Reg. 74122, 74184 (Nov. 31, 2011); 75 Fed. Reg. 72128, 71862 (Nov. 24, 2010); 74 Fed. Reg. 60316, 60409 (Nov. 20, 2009); 73 Fed. Reg. 68502, 68572 (Nov. 18, 2008); 2008 Final Rule, at 66664.

⁴² See 2015 Final Rule, at 66820.

⁴³ See *id.*, at 66819.

⁴⁴ See *id.*, at Addendum B.

⁴⁵ See 2016 Final Rule, at APC Cost Statistics.

⁴⁶ See *id.*, at Addendum B.