K0009/E1229 CODE RATIONALE

FOR

TiLite ZRA

Introduction:

On December 21, 2005, the SADMERC officially notified TiLite that the SADMERC had verified that the correct HCPCS codes for the TiLite ZRA are K0009 or E1229--depending on the exact dimensions of the chair[1]. A copy of the SADMERC's letter to TiLite is posted in the "Funding" section of www.tilite.com.

While the SADMERC determination should satisfy most reimbursement sources other than Medicare, technically the SADMERC determination only applies to Medicare billing. Therefore, this document sets forth a summary of the reasons why TiLite believes that these are the correct codes for the TiLite ZRA for all reimbursement sources. Many of these reasons were included in our code verification request to the SADMERC and, presumably, were relied upon by the SADMERC in reaching its conclusion.

Functional, Physical and Technological Differences from Existing Codes:

The TiLite ZRA represents the current state-of-the-art in rigid manual wheelchair design, whereas the existing manual wheelchair HCPCS codes reflect the state-of-the-art in manual wheelchairs from the 1980's. Being state-of-the-art, the TiLite ZRA is significantly different from K0005 and E1237 wheelchairs. These differences include: (1) functional differences, including lower weight; (2) physical differences; and (3) technological differences. Each of these differences will be addressed below. The long-term use of manual wheelchairs has been proven to result in a significant likelihood that the wheelchair user will experience upper limb pain and/or injuries to the wrist, elbow and/or shoulder. Therefore, while these functional, physical and technological differences are important, more important is the fact that the TiLite ZRA wheelchair presents a significant opportunity to improve patient health outcomes for long-term wheelchair users.

Customized Fit versus Adjustability

The TiLite ZRA wheelchair achieves as close as possible to ideal patient fit by using advanced computer aided design and flexible manufacturing techniques to enable TiLite to custom build each wheelchair to the exact dimensions of the patient. Each TiLite ZRA wheelchair is made to measure based on measurements of the patient taken by his or her physician, clinician or supplier. Using computer aided design software, TiLite creates full-scale drawings for each chair based on such measurements. Finally, using flexible manufacturing techniques, rather than mass-production assembly lines, the chair is built to the patient's unique specifications. In

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[1] *Adult Codes*: According to the DMERC Medical Policy for Manual Wheelchair Bases and the letter dated December 21, 2005 from the SADMERC to TiLite (a copy of which is posted in the "Funding" section at www.tilite.com), a TiLite ZRA manual wheelchair with a seat width and depth of 15" or more is considered to be an adult size wheelchair and must be billed as K0009.

Pediatric Codes: According to the DMERC Medical Policy for Manual Wheelchair Bases and the letter dated December 21, 2005 from the SADMERC to TiLite (a copy of which is posted in the "Funding" section at www.tilite.com), a TiLite ZRA manual wheelchair with a seat width and/or depth of less than 15" is considered to be a pediatric size wheelchair and must be billed as E1229.

fact, based on the various measurements which are required to order a TiLite ZRA, there are more than 15.2 million different frames that can be built by TiLite. Moreover, this extremely high number of combinations does not take into account rear wheel and tire combinations which can increase the total more than seven-fold and non-standard frame specifications offered by TiLite's "Designs Unlimited"department. Accordingly, if the wheelchair user is not measured correctly, the resulting TiLite ZRA wheelchair will not properly fit the intended user and it will not properly fit any other user. For this reason, TiLite ZRA wheelchairs are not returnable or resalable.

The design of TiLite products emphasizes welding the finished product as much as possible rather than using nuts, bolts and brackets to assemble the various parts of the wheelchair frame. Fully welded products are less adjustable, but weigh less and are more durable because there are fewer components that can come loose over time. They also provide a more rigid product, which results in a product that rolls truer and with less loss of momentum when being propelled by the user.

By contrast, K0005 wheelchairs are required only to have an adjustable rear axle position, thereby facilitating adjustment of the center of gravity. E1237 wheelchairs are required to be "adjustable", although the degree of adjustability is not defined in the DMERC Medical Policy for Manual Wheelchair Bases. In practice, almost all K0005 and E1237 wheelchairs are designed to be fully adjustable—meaning they are designed to permit the user to adjust front seat height, rear seat height, center of gravity, seat back height, seat back angle, etc.—and, in the case of E1237 wheelchairs, growable as the child grows. This high degree of flexibility may make the chair easier to order because less precision is required of the supplier, but each aspect of adjustability adds weight to the product and is achieved with some type of clamp or bracket that must be bolted to or through the frame. These components represent a weak point in the design that results in a heavier, less durable product.

Armrests

Armrests are considered to be standard equipment on K0005 and E1237 wheelchairs. However, wheelchair propulsion studies clearly demonstrate that armrests actually impede the use of ideal propulsion techniques. The most ergonomically correct propulsion stroke, given the biomechanics of the human shoulder and arm involves keeping the arms as close as possible to the body when propelling, thereby facilitating a longer, smoother stroke. Accordingly, the TiLite ZRA does not include armrests as standard equipment, which further distinguishes it from K0005 and E1237 wheelchairs.

Materials

TiLite ZRA wheelchairs generally utilize aerospace grade titanium alloys and other advanced materials to construct the wheelchair frame. By contrast, K0005 and E1237 wheelchairs generally utilize 6061-T6 aluminum or 4130 steel alloys. Aerospace grade titanium alloys represent a significant advance in metallurgy as compared with aluminum or steel. Titanium has a significantly higher strength-to-weight ratio, which results in the ability to create far lighter wheelchair frames than frames made with either aluminum or steel. Titanium also will not rust, which is an advantage compared with steel, and it will not corrode, an advantage over both aluminum and steel. Titanium will not "work-fatigue," which is a physical process whereby a metal subjected to repeated stress will, over time, become brittle making it prone to crack.

Lastly, titanium acts as a natural shock absorber, meaning that it absorbs vibration to a far greater degree than either aluminum or steel. When used in a wheelchair, this property of

titanium has two distinct advantages for wheelchair users. First, by absorbing more vibration, the wheelchair will roll more smoothly over rough terrain. As a result, the wheelchair will bounce around less, which means that, with each propulsion stroke, more of the user's energy results in forward movement. Second, less vibrational energy will be transmitted to the wheelchair user. This is a significant benefit as many wheelchair users, particularly those with spinal cord injuries, are subject to significant back pain resulting from the vibrations transmitted by aluminum and steel wheelchairs. This advantage presented by titanium is so significant that many leading physicians recommend titanium chairs over suspension chairs for their patients who are subject to such back pain.

Unlike a traditional K0005 or E1237 wheelchair, a TiLite ZRA wheelchair made from titanium will almost never need to be replaced. As proof of this fact, in the more than five (5) years that TiLite has been marketing its titanium wheelchairs, TiLite has experienced a frame failure rate of less than one-half of one percent (0.5%).

Weight

The TiLite ZRA is significantly different from K0005 and E1237 wheelchairs. The most significant difference is weight-related, but numerous health benefits flow from that difference. A 16" x 16" adult size TiLite ZRA weighs 19.9 lbs including 24" rear wheels, standard footrests and all other standard accessories. The following table indicates how significant this low weight is relative to competing products from Quickie and Invacare. All information regarding Quickie and Invacare products is available on their respective websites.

Wheelchair Manufacturer and Model	Manufacturer Recommended Code	Weight With Standard Accessories but Without Wheels	Total Weight
TiLite ZRA (rigid)	E1229	11.7 lbs (12" x 12" w/footrests)	18.8 lbs (12" x 12" w/22" wheels and footrests)
TiLite ZRA (rigid)	K0009	12.4 lbs (16" x 16" w/footrests)	19.9 lbs (16" x 16" w/24" wheels and footrests)
Zippie GS (rigid or folding)	E1237	Not Available	"Approx. 25 lbs *w/o footrests*"
Zippie (rigid)	E1237	Not Available	"Approx. 24 lbs *w/o footrests*"
Terminator Jr. (rigid)	E1237	Not Available	"Complete chair from 25-27 lbs depending on size and options"
Invacare A-4 (rigid)	K0005	14.5 lbs (excludes accessories; 15" x 16")	24.0 lbs (16" x 16" including standard accessories)
Quickie ST/DT (rigid)	K0005	Not available	27.0 lbs (16" x 16" including standard accessories)
Quickie R2 (rigid)	K0005	Not available	22.5 lbs (16" x 16" including standard accessories)

The foregoing table makes it clear that the adult size TiLite ZRA has a 2.6 lbs. to 6.1 lbs. weight advantage over the other adult size chairs and that the pediatric size TiLite ZRA has a 6.2 lbs. minimum weight advantage over the lightest of the other pediatric size chairs (the Terminator Jr. because the Zippie excludes footrests). By virtue of the weight savings, TiLite ZRA wheelchairs have two key advantages over K0005 and E1237 wheelchairs:

- they are easier to self-propel because rolling resistance is reduced-which is a function of both the lower weight and the vibration-absorbing properties of the materials used; and

- they are easier for the user to lift into and out of the user's vehicle when transferring to and from the user's vehicle.

With respect to self-propelling, an example demonstrates the magnitude of this advantage. The average manual wheelchair user pushes the pushrim 3500 times per day. Boninger, ML, Dicianno, BE, Cooper, RA, Towers, JD, Koontz, AM, Souza, AL. *Shoulder Magnetic Resonance Imaging Abnormalities, Wheelchair Propulsion & Gender*. Arch Phys Med & Rehab, 2003; Vol. 84:1615-1620. Assuming an average 4.5 lbs. weight savings and multiplying by 3,500, it is apparent that a user in a TiLite ZRA will push 15,750 lbs. less each day. That is more than 7.8 tons per day and more than 2,850 tons per year!

It has been noted that the life expectancy of persons with spinal cord injury is approaching that of the general population, and it is not uncommon for such people to self-propel in a manual wheelchair for 40 or 50 years. Therefore, the impact of the weight savings provided by TiLite ZRA wheelchairs becomes increasingly magnified over time. Over extended periods of time, use of the lightest possible wheelchair will (a) reduce the need for very expensive surgeries to repair upper limb injuries and the associated extended rehabilitation and convalescence, and (b) delay the need to transition long-term manual wheelchair users to more expensive power wheelchairs.

Long-Term Manual Wheelchair Use Is Proven to Increase Upper Limb Pain and Injury:

As more fully explained below, there are significant adverse health effects of the long term use of manual wheelchairs.

Studies of people with spinal cord injury ("SCI") have found that the incidence of Carpal Tunnel Syndrome ("CTS") among wheelchair users with SCI is between 40% and 66%. See Sie, I.H. et al., *Upper Extremity Pain in the Postrehabilitation Spinal Cord Injured Patient*, Arch Phys Med & Rehabil, 1992, Vol. 73:44-8 ("Sie, 1992"). Aljure, J. et al., *Carpal Tunnel Syndrome in Paraplegic Patients*, Paraplegia, 1985, Vol. 23:182-6. Gellman, H. et al., *Carpal Tunnel Syndrome in Paraplegic Patients*, J Bone & Joint Surg, 1988, Vol. 70:517-9. Gellman, H. et al., *Late Complications of the Weight-Bearing Upper Extremity in the Paraplegic Patient*, Clin Ortho & Related Research, 1988, Vol. 233:132-5 ("Gellman, 1988b").

Studies of people with SCI have found that the incidence of shoulder problems among wheelchair users with SCI is between 30% and 60%. See Sie, 1992. Gellman, 1988b. Pentland, W.E., et al., *Upper Limb Function in Persons with Long Term Paraplegia and Implications for Independence*, Paraplegia, 1994, Vol. 32:211-8. Ballinger, D.A. et al., *The Relation of Shoulder Pain and Range-of-Motion Problems to Functional Limitations, Disability and Perceived Health of Men with Spinal Cord Injury*, Arch Phys Med & Rehabil, 2000, Vol. 81:1575-81. Nichols, P.J. et al., *Wheelchair User's Shoulder? Shoulder Pain in Patients with Spinal Cord Lesions*, Scand J Rehabil Med, 1979, Vol. 11:29-32. Subbarao, J.V. et al.,

Prevalence and Impact of Wrist and Shoulder Pain in Patients with Spinal Cord Injury, J Spinal Cord Med, 1994, Vol. 18:9-13 ("Subbarao, 1994").

Sie, 1992, found that 59% of individuals with tetraplegia and 41% of individuals with paraplegia experience significant pain in their upper limbs. "Significant pain" is defined as pain requiring analgesic medication, pain associated with two or more activities of daily living ("ADLs") or pain severe enough to result in cessation of activity.

Upper limb pain correlates with increased need for assistance with functional activities and decreased independence. See Dalyan, M. et al., *Upper Extremity Pain after Spinal Cord Injury*, Spinal Cord, 1999, Vol. 37:191-5 ("Dalyan, 1999"). In this study, 26% of persons with pain required additional help with functional activities and 28% reported that pain resulted in limitations on independence.

Employment status is adversely affected by upper limb pain—individuals with SCI who experience upper limb pain are three times more likely to be unemployed and less than half as likely to be employed full-time. See Dalyan, 1999.

Reducing Forces at the Wheelchair Pushrim During Self-Propulsion Proven to Reduce the Adverse Health Effects of Long-Term Manual Wheelchair Use:

Individuals who apply higher forces to the wheelchair pushrim when self-propelling will, over time, experience reduced sensory amplitude during nerve conduction studies. See Boninger, M.L. et al., *Wheelchair Pushrim Kinetics: Weight and Median Nerve Function*, Arch Phys Med & Rehabil, 1999, Vol. 80:910-15 ("Boninger, 1999"). As the combined weight of the user and the wheelchair increases, the force required to propel the wheelchair increases. Boninger, 1999.

In a study of individuals who had nerve conduction studies and biomechanical analyses two years apart, it was shown that those whose pushrim forces were a high percentage of their body mass had worse nerve conduction studies at follow-up and were less effective at propelling their wheelchairs. See Fronzcak, K. et al., *Wheelchair Propulsion Biomechanics, Weight and Median Nerve Damage: A Longitudinal Study*, 26th Annual RESNA Conference, Atlanta, GA, 2003.

These long-term study results should come as no surprise given the design, function and technological advances described above. Because a TiLite ZRA wheelchair has lower rolling resistance than competing K0005 and E1237 wheelchairs, users of TiLite ZRA wheelchairs are able to (a) minimize the frequency of the propulsive strokes necessary to self-propel the wheelchair, and (b) reduce the force required to self-propel the wheelchair.

Manual Wheelchair Codes are Being Revised:

With respect to wheelchair codes, the HCPCS coding system uses wheelchair weight as a primary factor to differentiate among adult manual wheelchair codes (but, inexplicably, not among pediatric wheelchair codes). For example, when the K0005 HCPCS Code was established in 1994, CMS recognized a new, lighter-weight standard for manual wheelchairs. The K0005 Ultralightweight Wheelchair code reduced wheelchair weight by 4 lbs, or 12%, over the existing K0004 High-Strength, Lightweight Wheelchair Code. Today, state-of-the-art wheelchairs, both adult and pediatric, can save a further 5 to 10 lbs. or more of weight.

The following chart indicates the existing and proposed HCPCS codes and relative weight reductions between codes (excluding the K0002 code that is merely a variation of the K0001 code):

HCPCS Code	Code Name	Wheelchair Weight	Weight Reduction from Preceding Code	% of Weight Reduction from Preceding Code
K0001	Standard Wheelchair	>36 lbs.	--	--
K0003	Lightweight Wheelchair	34-36 lbs.	0 to 2 lbs.	0% to 5.6%
K0004	High-Strength Lightweight Wheelchair	<34 lbs.	2 lbs.	5.6%
K0005	Ultralight-weight Wheelchair	<30 lbs.	4 lbs.	11.8%
Not yet determined	**Under 20-Lbs. High-Activity Wheelchair**	**<20 lbs.**	**10 lbs.**	**33.3%**

At the time the K0005 code was created, K0004 already existed. Since it was determined that a new K0005 code was necessary, it logically follows that it must have been determined that the existing K0004 code was inadequate to describe a class of products that promised an 11.8% weight reduction. Following that logic, the existing K0005 code cannot be adequate to describe a class of products that delivers a 33.3% weight reduction.

In the ten years since CMS last visited the subject of the basic manual wheelchair codes, substantial amounts of time and money have been invested in wheelchair research and development by TiLite and other manufacturers in an effort to:

- reduce wheelchair weights, thereby reducing the frequency and severity of joint deterioration, injury and pain experienced by wheelchair users;

- increase the durability of wheelchairs to prevent wheelchair users from being stranded or house-bound due to the downtime involved with wheelchair repairs and replacement; and

- improve wheelchair functionality, thereby facilitating much greater integration of wheelchair users into society and significantly contributing to the fulfillment of the goals of the American with Disabilities Act.

In 2004, CMS announced that it was reviewing, and expected to extensively revise, the power and manual wheelchair codes. At the request of the SADMERC, in April 2005 a group representing NCART (including TiLite, Sunrise Medical and Invacare) met with the SADMERC to discuss necessary changes in manual wheelchair codes. Since then, NCART has been working closely with the SADMERC on a complete overhaul of the manual wheelchair codes in a fashion similar to the overhaul of the power wheelchair codes. At this time, TiLite is optimistic that the new codes will more accurately reflect the state-of-the-art in manual wheelchair design—in other words, there will be codes that reflect the extremely low weight and highly customized ("made-to-measure") nature of TiLite wheelchairs. We anticipate that new codes will be adopted in 2006 or 2007.

By verifying that the correct HCPCS codes for the TiLite ZRA are K0009 and E1229, both of which are "miscellaneous" codes, the SADMERC has determined that this product does not properly fit within any of the specific manual wheelchair codes due to the "made-to-measure" nature of this product. TiLite intends to continue to work with the SADMERC to ensure that the upcoming overhaul of the manual wheelchair HCPCS codes will include a code for "made-to-

measure" products such as the TiLite ZRA so that use of the miscellaneous code will no longer be necessary.

Conclusions:

TiLite ZRA wheelchairs present five distinct advantages over K0005 and E1237 wheelchairs:

(1) By utilizing space-age materials with extremely high strength-to-weight ratios, the TiLite ZRA has significantly lower mass (weight) than K0005 and E1237 wheelchairs, which need only weigh less than 30 lbs.

(2) Because of the space-age materials that are used, TiLite ZRA wheelchairs are significantly more durable than K0005 and E1237 wheelchairs.

(3) Because TiLite ZRA wheelchairs are lighter and more customized than K0005 and E1237 wheelchairs, they fit the end user better resulting in improved ergonomics and increased functionality.

(4) Because TiLite ZRA wheelchairs have improved ergonomics and increased functionality, end users will achieve the maximum degree of independence—they will be able to move faster, negotiate rougher terrain, climb inclines and other obstacles (e.g., door sills) with greater ease, and travel farther.

(5) Because TiLite ZRA wheelchairs have improved ergonomics and increased functionality, end users will significantly reduce their risk of upper limb injury from long-term manual wheelchair use.

Because of the above advantages and because it is highly likely that the coding structure will be completely revised in the near future in a manner that recognizes the technological advances of the past decade and the need to provide wheelchair users with extremely light, highly customized products, such as the TiLite ZRA, we believe it is inappropriate to code the TiLite ZRA as K0005 or E1237. Instead, we believe that K0009 (for adult size chairs) or E1229 (for pediatric size chairs) is more suitable until new, more appropriate codes are created. Most importantly, as of December 21, 2005, the SADMERC now agrees that these are the correct codes.

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