

THE BIO♦BACK

The most comfortable name in back pain relief!





The Market

There is no shortage of back pain statistics. According to the U.S. Department of Health and Human Services; Lower-Back pain currently affects almost 60 million U.S. adults, indicating that over 25% of adults are suffering from lower back pain at any given moment.

The following is an excerpt from a U.S. Department of Health and Human Services (CDC) report¹ based upon 2007 statistics regarding lower back pain:

Age Group (18 & Older)	Total U.S. Adult Population	Adults Suffering Lower Back Pain	Percentage
18-44 Years	110,890,000	24,555,000	22.1%
45-64 Years	76,136,000	21,860,000	28.7%
65 Years and Over	36,155,000	10,655,000	29.5%
Total U.S. Adults	223,181,000	57,070,000	25.6%

These statistics indicate the percentage of the population suffering from low back pain increases with age to 29.5% for adults 65 years and older.

A number of additional, commonly published, statistics support why there is a need for an effective solution to low-back pain, the Bio-Back:

1. **Mayo Clinic:** Back pain is a common complaint. Most people in the United States will experience low back pain at least once during their lives. Back pain is one of the most common reasons people go to the doctor or miss work. <http://www.mayoclinic.com/health/back-pain/DS00171>
2. **WebMD:** Back pain affects 80% of Americans at some time in their lives. <http://www.webmd.com/back-pain/default.htm>
3. **Spine Magazine:** Recurrence rates after a single episode of back pain are staggeringly high, with 60% to 86% of patients reporting recurrent back pain symptoms. [Spine (2001) 26 (11): E243-E248]

¹ Pleis JR, Lucas JW. Summary health statistics for U.S. adults: National Health Interview Survey, 2007. National Center for Health Statistics. Vital Health Stat 10(240). 2009. http://www.cdc.gov/nchs/data/series/sr_10/sr10_240.pdf



Press release excerpt.

Congress of Chiropractic State Associations (COCSA) Grants Bio-Back Lumbar Orthosis Their Seal of Approval

By: PR Newswire | 29 Apr 2010 | 01:40 PM ET

DUBLIN, Ohio, April 29, 2010 /PRNewswire via COMTEX/ -- COCSA and Medolutions, LLC are pleased to announce that the **Bio-Back Lumbar Orthosis has been awarded the COCSA Seal of Approval**. The patented Bio-Back is a licensed product of Medolutions, LLC and is clinically proven to help relieve back pain and restore function. The Bio-Back's small, light-weight design makes it an effective tool in the treatment of low back pain.

About COCSA The Congress of Chiropractic State Associations was founded in 1969 with the mission of providing an open nonpartisan forum for the advancement of the chiropractic profession through service to its member state associations. **The COCSA Seal of Approval is granted to products or services deemed to have exceptional value to our state association members or the chiropractic profession. In speaking of the Bio-Back, First Vice President Dr. Kate Rufolo said, "On behalf of the Board, let me say that the Bio-Back represents the best of what is out there to improve the profession and to benefit our patients. We look forward to working with Medolutions."** Additional information about COCSA is available at <http://www.cocsa.org>.



The Opportunity

Your patients are currently searching for a solution to their back pain. Generate new revenue from existing patients.

Empower your patients to live everyday back pain free. They will thank you for it!

Enhance your already successful patient relationships. Strong relationships mean loyal patients.

Generate patient referrals. Word of mouth advertising is the best advertising.

Medicare reimbursed solution to back pain. The Bio-Back average allowable is \$370.

Order processing for the Bio-Back is similar to those you are already using. Implementation is easy.

Risk Free Marketing.

Medolutions provides the initial supply of flyers that can be sent with outgoing shipments.



Bio-Back Information



Reimbursed under HCPCS Code L0627

Lumbar Orthosis, sagittal control, with rigid anterior and posterior panels, posterior extends from L-1 to below L-5, vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated includes fitting and adjustment.

U.S. Patent number 5,443,697.

FDA registered as a Non-invasive medical device.

Pilot clinical study demonstrates how and why the Bio-Back is effective at relieving back pain.

Manufactured by VentLab, Mocksville, NC.

Average Medicare Fee Schedule \$370.00.

Standard Size Bio-Back fits a 22" to a 50" Waist Size. Large Size Bio-Back fits up to a 78" Waist Size.

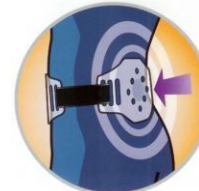
Packaged 10 Bio-Backs per case.

Unit packaging includes the Bio-Back, Written Instructions and a DVD in seven languages containing an Introduction, Fitting Instructions and Testimonials.

THE BIO♦BACK



Patented Features



Bilateral Opposing Force

Provides support to the lumbar and abdominal regions

Promotes core muscular stability

Counter-force pressure reduces the load on intervertebral discs and facet joints

Reduce the strain on key endurance muscles in the lower back

Lumbar Dome

Automatically improve posture to a neutral spine position

Alleviate pain and promote better body mechanics

Patented features provide immediate relief from back pain associated with:

- Strain/sprain injuries
- Mechanical low back pain
- Herniated or ruptured discs
- Spondylolisthesis, Spondylolysis
- Degenerative conditions of the spine involving the discs, joints or nerve roots in the lower back

Bio-Back helps patients:

- Recover from injury
- Protect against re-injury
- Enjoy life's activities with confidence



Real Results

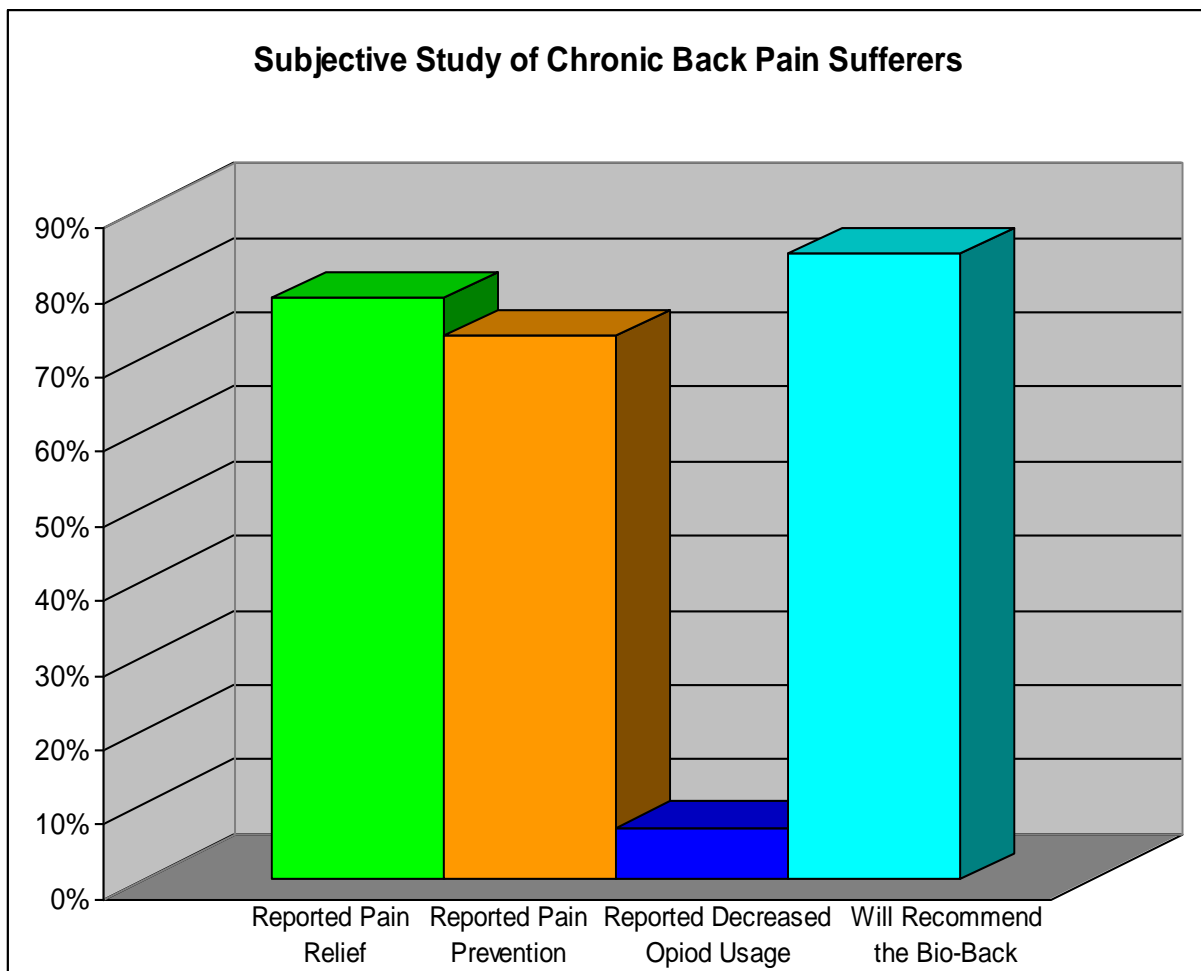
A Pain Management Clinic conducted a subjective survey of chronic back pain sufferers using the Bio-Back for various lengths of time. The following results were reported:

78% Reported Pain Relief

73% Reported Pain Prevention

7% Reported a Decrease in Opioid Consumption

84% Would Recommend the Bio-Back





Real Science

The effect of a novel lumbar orthosis on paraspinal muscle activity: a pilot study

Charles W. Lindquist Jr. D.C. DACNB

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ABSTRACT

Modifying the activity and improving the endurance of lumbar musculature during dynamic and static activities is a key component of treatment for low back pain. This paper presents a pilot study assessing the effect of a novel lumbar orthosis on lumbar muscle activity. Nine asymptomatic volunteers (7 males and 2 females) ranging in age from 22 to 55 years were recruited and six subjects were included in the final analysis. The electromyographic (EMG) signals of the paraspinal muscles at the L4 vertebral level were assessed while participants stood in a neutral position with or without the orthosis. When wearing the orthosis, the electrical muscle activity was reduced by 51.3% ($p=.03$) and 38.8% ($p=.09$) for longissimus and multifidus muscles, respectively. Collectively, use of the orthosis reduced the activity of the paraspinal musculature by 46.2% ($p<.05$). This pilot study suggests that this novel orthosis may provide external stability to the spine and relieve muscle strain by reducing the recruitment of the paraspinal muscles. Further well-controlled outcomes studies are needed to validate the effectiveness of this orthosis in a large symptomatic patient population.



Medicare Information

Source: <https://www.dmepdac.com/dmecsapp/do/productsearch>

This list reflects products which have been submitted by the manufacturer for a HCPCS coding verification review. The assignment of a HCPCS code to the product(s) should in no way be construed as an approval or endorsement of the product(s) by the Noridian, DMERCS, or Medicare, nor does it imply or guarantee claim reimbursement. This list reflects the latest product information on file, therefore, the information displayed in the results table may differ from the search criteria you entered for manufacturer name, product name, and model number.

3 results found, displaying 1 to 3

Product Name	Manufacturer/Distributor	Model Number	HCPCS Code	Effective Begin Date	Effective End Date	Comments
BIO-BACK	MEDOLUTIONS, LLC		L0627	01/01/2006		
BIO-BACK	MEDOLUTIONS, LLC		K0636	04/01/2004	12/31/2005	
BIO-BACK	MEDOLUTIONS, LLC		L1499	02/05/2003	03/31/2004	



The lumbar orthosis Medicare coverage policy is not a “Diagnosis Specific Medical Policy”.

Indications and Limitations of Coverage and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity.

For an item to be covered by Medicare, a written signed and dated order must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not medically necessary.

A thoracic-lumbar-sacral orthosis (L0450-L0492), lumbar orthosis (L0625-L0627) or lumbar-sacral orthosis (L0628-L0640) is covered when it is ordered for one of the following indications:

- 1) To reduce pain by restricting mobility of the trunk; or
- 2) To facilitate healing following an injury to the spine or related soft tissues; or
- 3) To facilitate healing following a surgical procedure on the spine or related soft tissue;
or
- 4) To otherwise support weak spinal muscles and/or a deformed spine.



**PHYSICIAN ORDER FORM BIO-BACK LUMBAR ORTHOSIS
(COMPANY NAME, PHONE & FAX NUMBER)**

Physician Name:	NPI:
Phone:	Fax:

Patient Name:	DOB:	Insurance/HIC#:
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	<p>The Bio-Back can be covered if the coverage criteria are met. We <u>are required by the patient's Medicare or Insurance to have the information below prior to shipping.</u></p> <p><i>PLEASE FAX THIS FORM AFTER IT IS COMPLETED, SIGNED AND DATED</i></p>
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ALL SECTIONS MUST BE COMPLETED

- 1** Lumbar orthosis is covered when it is ordered for one of the following indications:
Circle Y for Yes, N for No, D for Does Not Apply.
- Y N D 1) To reduce pain by restricting mobility of the trunk; or
- Y N D 2) To facilitate healing following an injury to the spine or related soft tissues;
 or
- Y N D 3) To facilitate healing following a surgical procedure to the spine or related
 soft tissues;
- Y N D 4) To otherwise support weak spinal muscles and/or a deformed spine.

2 Estimated Length of Need	<input type="radio"/> LIFETIME <input type="radio"/> Other: _____
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3 ICD-9 DIAGNOSIS CODE(S)	
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Prescribing physician, as noted above, must sign written order for Medicare/insurance to authorize payment. BY SIGNING BELOW, I AUTHORIZE the use of this document as a legal prescription, and certify that the lumbar orthosis is medically necessary and reasonable for the above patient. I will maintain an original signed copy of this order in my medical records and make it available to Medicare, their authorized agents or other insurer, if required.

 _____	 _____
<i>Original signature required, no stamps permitted</i>	<i>No date stamps permitted</i>



MEDICAL CONDITIONS FOR WHICH BIO♦BACK CAN PROVIDE PAIN RELIEF

Note: Most common conditions, not all inclusive.

Common Name(s)	Diagnosis Code - Technical Name & Definition	Common Explanation And Causes
<p>Ankylosing spondylitis - Spondylitis, - Spinal pain</p>	<p>720.2 Ankylosing spondylitis - Sacroiliitis, not elsewhere classified (Inflammation of sacroiliac joint)</p>	<p>Symptoms may include pain and/or stiffness from the neck down to the lower back. Vertebrae may grow (or fuse) together making the spine more rigid. This condition may be mild or severe, and may lead to a stooped-over posture. Spondylitis may also cause pain in some of the ligaments and tendons that attach to bones.</p>
<p>Backache - Aching back, - back pain, - back problems, - low back pain, - lower back pain, - lumbago</p>	<p>724.5 Backache unspecified - Vertebrogenic (pain) syndrome NOS</p> <p>724.6 Backache (postural), sacroiliac</p>	<p>Back pain or low back pain is one of the most common physical complaints among American adults. Back pain includes sore muscles and tendons as well more serious back conditions. One of the more common types of back pain comes from straining the bands of muscles surrounding the spine and most commonly this happens in the curve of the lower back.</p> <p>Frequently, the causes of back pain have developed over a long period of time and happen because of bad habits developed over time. These bad back habits include:</p> <ul style="list-style-type: none"> ○ Poor posture ○ Overexertion ○ Sitting incorrectly ○ Lifting, pushing or pulling things carelessly
<p>Back Strain or Sprain - back injury, - Muscle pain, - Muscle strain, - Muscle sprain</p>	<p>846.0 Sprains and strains, Lumbosacral (joint) (ligament)</p> <p>847.2 Sprains and strains, Lumbar</p>	<p>Back sprain or strains frequently result from an injury to the ligaments or muscles in the back. Injuries generally occur when performing activities that you do not do very often, such as lifting a heavy object or doing yard work, which cause additional strain on back muscles. Minor injuries also may occur from falling, tripping, or sudden or excessive twisting of the spine. Severe</p>

		back injuries may result from car accidents, more significant falls or from direct blows to the back or other impacts which compress the spine.
Fibrous Ankylosis - nerve pain, - nerve root pain	724.9 Ankylosis of spine NOS, compression of spinal nerve root NEC, spinal disorders NOS	Fibrous ankylosis is the impairment of mobility due to the overgrowth (or proliferation) of fibrous tissue in the joints, which may also create pressure on the spinal column or spinal nerve root(s).
Herniated disc(s) and Other Intervertebral disc disorders - bulging disc(s), - degenerative disc disease - disc problems, - ruptured disc(s), - slipped disc(s)	722.10 Lumbar intervertebral disc without myelopathy (Lumbago or sciatica due to displacement of intervertebral disc. Neuritis or radiculitis due to displacement or rupture of lumbar intervertebral disc) 722.32 Schmorl's nodes - Lumbar region 722.52 Degeneration of lumbar intervertebral disc 722.73 Intervertebral disc disorder with myelopathy - Lumbar region 722.83 Postlaminectomy syndrome - Lumbar region 722.93 Other and unspecified disc disorder - Lumbar region	Herniated discs may occur as the spinal discs degenerate or grow thinner. The jellylike central portion of the disc bulges out of the central cavity and pushes against a nerve root. Intervertebral discs generally begin to degenerate by the third decade of life. Herniated discs are found in a third of adults older than 20. Only 3% of these, however, produce symptoms of nerve impingement. When alterations in the disc progress to degeneration it is called spinal degeneration.

<p>Muscle spasms and muscle weakness - chronic back pain, - Mechanical low back pain or lower back pain,</p>	<p>728.4 Laxity of ligament</p> <p>728.5 Hypermobility syndrome</p> <p>728.85 Spasm of muscle</p> <p>728.87 Muscle weakness (generalized)</p>	<p>Low back pain related to muscle tension or spasm may be the result of frequent or ongoing tension or stress. If untreated or unresolved, these factors may result in chronic (or long term) back pain. Frequently, this leads to a downward spiral of inactivity, which weakens the muscles causing more pain and may lead to depression.</p> <p>When aches and spasms are vague and not related to a specific injury, they may also be symptoms of depression or other medical conditions. It's important to see a doctor for a medical evaluation to determine the cause.</p>
<p>Musculoskeletal pain syndromes</p>	<p>729.10 Myalgia and myositis, unspecified</p> <p>729.20 Neuralgia, neuritis, and radiculitis, unspecified.</p>	<p>Musculoskeletal pain syndromes, such as myofascial pain syndromes and fibromyalgia can produce low back pain. Myofascial pain is characterized by pain and tenderness over localized areas, loss of range of motion in the involved muscles, and radiating pain restricted to a peripheral nerve.</p> <p>Fibromyalgia results in pain and tenderness in numerous areas (trigger points) when touched, which includes the low back. This may result in stiffness, fatigue, and muscle aches</p>
<p>Osteoarthritis - facet joint arthrosis, - facet joint arthritis, - osteoporosis of the back,</p>	<p>721.90 Osteoarthritis, spine, spinal NEC (see also Spondylosis)</p>	<p>Arthritis is a general term that means inflammation in joints. Osteoarthritis is a degenerative joint disease and is the most common type of arthritis. It is caused by a breakdown of cartilage in joints and can occur in almost any joint in the body. It most commonly occurs in the weight bearing joints of the hips, knees, and spine. As cartilage in a joint becomes stiff and loses its elasticity, it becomes more susceptible to damage. Over time, the cartilage may wear away, greatly decreasing its ability to act as a shock absorber. As the cartilage deteriorates, tendons and ligaments stretch, causing pain. If the condition worsens, the bones could rub against each other.</p>



<p>Rheumatoid arthritis</p>	<p>720.0 Rheumatoid arthritis, spine</p>	<p>Rheumatoid arthritis is a type of chronic arthritis that typically occurs in joints on both sides of the body. Symptoms of rheumatoid arthritis include: joint pain and swelling; Stiffness, especially in the morning or after sitting for long periods; and fatigue.</p> <p>Rheumatoid arthritis affects people differently. For some people, joint pain develops gradually over several years. In others, rheumatoid arthritis may progress rapidly. Other people may have rheumatoid arthritis for a limited period of time and then enter a period of remission.</p>
<p>Sciatica - leg pain,</p>	<p>724.3 Sciatica - Neuralgia or neuritis of sciatic nerve</p>	<p>Sciatica is a common type of pain affecting the sciatic nerve, a large nerve extending from the lower back down the back of each leg.</p> <p>Sciatica may only affect one side of the lower body and generally the pain extends from the lower back all the way through the back of the thigh and down through the leg. Depending on where the sciatic nerve is affected, the pain may extend all the way to the foot or toes. For some people, sciatica pain can be severe and debilitating, while for others the pain might be infrequent and irritating.</p>
<p>Spinal stenosis</p>	<p>724.02 Spinal stenosis Lumbar region</p>	<p>Spinal stenosis is the narrowing of spaces in the spine (backbone) which causes pressure on the spinal cord and/or nerves. That vast majority (about 75%) of cases of spinal stenosis occur in the low back (lumbar spine). Frequently, the narrowing of the spine associated with stenosis compresses the nerve root, which can cause pain along the back of the leg. The most common causes of spinal stenosis are aging, arthritis, heredity, instability of the spine or trauma. The two most common forms of arthritis that may affect the spine are osteoarthritis and rheumatoid arthritis.</p>



<p>Spondylolisthesis</p>	<p>738.4 Spondylolisthesis (lumbosacral), acquired, degenerative, traumatic,</p> <p>756.12 Spondylolisthesis (congenital) (lumbosacral),</p>	<p>Spondylolisthesis is a condition in which one bone in your back (vertebra) slides forward over the bone below it. It most often occurs in the lower spine (lumbosacral area). This may lead to your spinal cord or nerve roots being squeezed and can cause back pain and numbness or weakness in your legs. Sometimes, when a vertebra slips out of place, you may have no symptoms for years. Then, you may have pain in your low back or buttocks. Muscles in your leg may feel tight or weak.</p>
<p>Spondylosis</p>	<p>721.3 Lumbosacral spondylosis without myelopathy - Lumbar or lumbosacral (arthritis, osteoarthritis, spondylarthritis)</p>	<p>Osteoarthritis of the spine sometimes is called spinal spondylosis, or spondylosis. <i>See osteoarthritis for more information.</i></p>



L0627 vs. L0631

Both types of braces are reimbursed by Medicare and other payors. Following is the description of both HCPCS Codes:

L0627 LUMBAR ORTHOSIS, SAGITTAL CONTROL, WITH RIGID ANTERIOR AND POSTERIOR PANELS, POSTERIOR EXTENDS FROM L-1 TO BELOW L-5 VERTEBRA, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PADDING, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

L0631 LUMBAR-SACRAL ORTHOSIS, SAGITTAL CONTROL, WITH RIGID ANTERIOR AND POSTERIOR PANELS, POSTERIOR EXTENDS FROM SACROCOCCYGEAL JUNCTION TO T-9 VERTEBRA, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PADDING, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

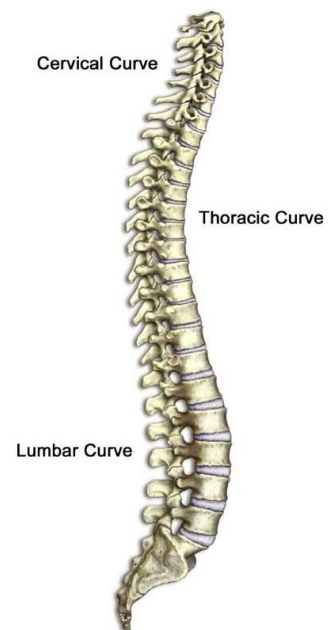
There are three basic coverage criteria that apply to everything reimbursed by Medicare:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

Number 2 says, “to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

Considering that approximately 90% of back conditions involve the lower back, then an L0631 brace that extends to the T-9 vertebra of the thoracic spine does not meet the “reasonable and necessary” test of coverage.

Therefore it is improper to bill Medicare for an L0631 where a patient has a medical condition that only involves the lower back and an L0627 would be reasonable and necessary to treat the patient.





BIO-BACK PURCHASE AGREEMENT

Medolutions, LLC ("the Company") is the licensed manufacturer/distributor of the Bio-Back a prefabricated lumbar orthosis designed to reduce back pain. _____, (Customer) desires to enter into this Agreement for the wholesale purchase of the Bio-Back for resale to customers. This Agreement will begin on the start date (signature date) and will remain in effect until terminated by either party at any time. Termination shall be deemed effective upon one party giving thirty (30) days written notice.

Product Pricing and Payment Terms: The Company will wholesale the Bio-Back to Customer in accordance with the price schedule and product configurations as defined below. Payment is due within thirty (30) days from the invoice date and may receive a 5% discount for payments made by credit card at the time of the order. Invoicing shall occur upon the date of order unless otherwise mutually agreed upon. Customer needs to allow for between 6 and 10 days for orders to be fulfilled and customer shall be responsible for all freight charges associated with the delivery of the product including shipping on any expedited orders.

Customer understands and acknowledges that they are receiving a volume discounted price and are required under the terms of this agreement to keep pricing and related details confidential and private.

Case Quantities (10 per case)	
BB200	
Standard Size Bio-Back With Padded Sleeves	\$880.00 per cs/10
BB300	
Large Size Bio-Back With Padded Sleeves	\$940.00 per cs/10

Customer Contact Information and Authorized Persons: Customer has designated the following persons as having authorization to order product on Customer's behalf, and hereby recognizes its financial responsibility.

Authorized (Purchaser) Contacts:

Name Title Signature

Name Title Signature

MEDOLUTIONS, LLC

55 South High Street, Ste 200

DUBLIN, OH 43017

Telephone: (888) 978-7999

Facsimile: (888) 560-1743

CUSTOMER: _____

Street Address: _____

City / State / Zip: _____

Telephone: _____

Facsimile: _____

Signature: _____

Signature: _____

By: _____

By: _____

Title: _____

Title: _____

Date: _____

Date: _____



Contacts

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Kurt worked for Medicare for 7 years and has over 20 years experience with healthcare operations, reimbursement and regulatory compliance.

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Dr. Graff was in private practice for over 20 years and continues to provide Workers' Compensation oversight and IMEs for the State of Ohio

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