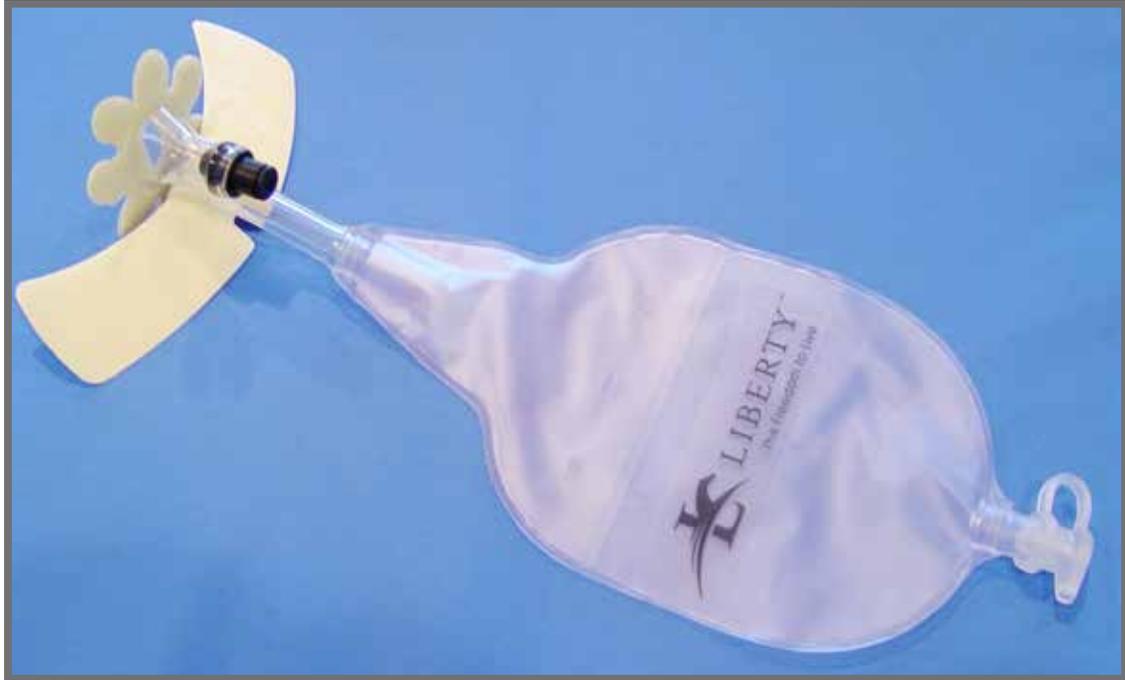




MEN'S
LIBERTY™
The Freedom to Live

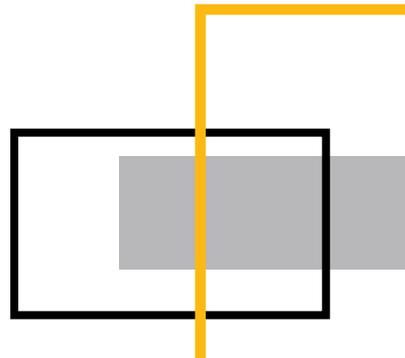
Health Care Professional Handbook



Discreet. Dignified. Dependable.

MensLiberty.com

Toll Free: (800) 814 - 3174





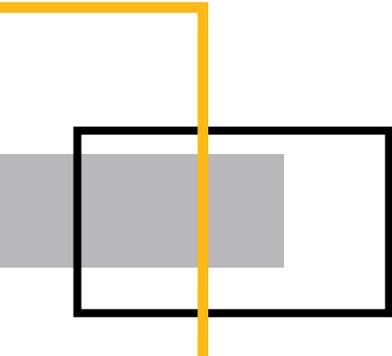
What Is Men's Liberty?

Men's Liberty is the newest, most innovative product for managing men's urinary incontinence in 50 years! It is manufactured by BioDerm, Inc. at our headquarters in Largo, FL.

Men's Liberty has been available for sale to consumers and medical facilities since 2006 when it was approved for billing under HCPCS Code A4326. It is covered by Medicare, most state Medicaids, Private Insurances, Workers Compensation and VA/TriCare.

Men's Liberty works with a network of distribution partners in the US and internationally to bring Men's Liberty straight to men's door steps. We have a dedicated customer care team on hand to answer questions, assist in placing orders and to support health care professionals and caregivers dealing with incontinence. Additional information can also be found on our blog and in various educational publications.

Learn more about Men's Liberty online at www.mensliberty.com or contact our customer care team at (800) 814-3174 for more information.



Manufactured by:





Dear Health Care Professional,

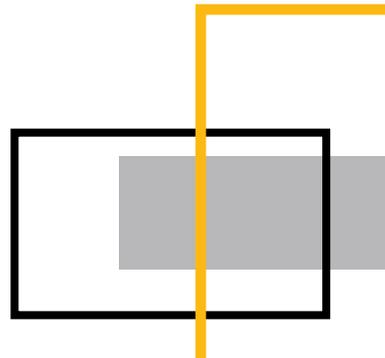
Thank you for taking the time to learn more about *Men's Liberty*. This is the first innovative product in more than 50 years! It is the **new standard of care** for men with urinary incontinence. In this booklet, we will address:

- *How Men's Liberty can improve outcomes and lower costs?*
- *What are the potential complications associated with outdated urinary management products?*
- *How do individuals and medical facilities currently manage urinary incontinence?*
- *What do these complications cost?*
- *What is Men's Liberty?*
- *What do men and their health care professionals think of Men's Liberty?*
- *Where can you learn more?*

In order to illustrate the benefits of Men's Liberty, we will be using a case study of a US military veteran with a spinal cord injury. However, the competitive products, complications and costs we will outline are equally applicable to incontinent men with many other potential diagnoses, including traumatic brain injury, ALS, multiple sclerosis, prostate cancer and more.

Sincerely,

The Men's Liberty Team





Case Study: Veteran with Spinal Cord Injury

There are an estimated 2.2 million veterans in the US today who suffered serious injuries while serving their country. Some of the most common injuries are spinal cord and traumatic brain injuries.

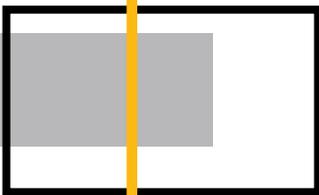
Medicine has improved by leaps and bounds in previous decades, allowing doctors to save the lives of many who would have died from their wounds just a few years ago. Yet many of these survivors are unable to regain an acceptable quality of life as a result both of their injuries and the health care system's inability to identify and implement higher standards of care for treatment of chronic issues like urinary incontinence.

Post Injury - The most common problems for veterans are issues with:

1. Pain
2. Incontinence/UTIs
3. Quality of Life/Dignity

To deal with these issues, they face outdated choices and standards of care that are painful and ineffective. In the following pages we will detail the failures of the current standards of care and how standards can be improved through the utilization of Men's Liberty.

CAUTION: SOME IMAGES MAY BE GRAPHIC.





Current Standards of Care: Why?

- Foleys, Condom Catheters, Pads -
“We have always done it this way”
- Large dominant companies want to keep their share of these markets:
 - *Diapers/Pads - 92% of the Total Market*
 - *Condom Catheter - 8% of the Total Market*
 - *Foleys - 1st Choice of the Surgical Market*
- They are cheap to buy but complications are expensive over time.
- Lack of understanding of the longer term downsides of each
- Lack of concern with the patient’s health and dignity

**STAY DRY AND COMFORTABLE ALL DAY,
EVERY DAY WITH MEN'S LIBERTY**





Men's Liberty

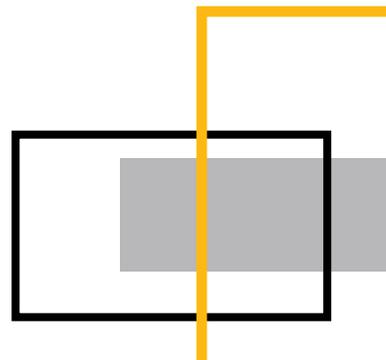
Features & Benefits

How Does It Work?

Men's Liberty is made from hydrocolloid, a medical adhesive that creates a secure, skin friendly seal around the urinary opening. Hydrocolloid has been used successfully in wound and ostomy treatment for decades.

Men's Liberty:

- Has a completely external design
- Fits most male anatomy
- Keeps men dry and comfortable
- Allows men to intermittent cath with the device in place
- Average wear time of 24-48 hours
- Replaces diapers, condom catheters and medically unnecessary Foley catheters
- Covered by Medicare, most state Medicaid, Private Insurances, Workers Compensation and VA/TriCare





Men's Liberty: Best Practice

- No indwelling catheter - no UTIs
- No threat to skin/tissue - skin friendly hydro-colloid covers only the head of the penis
- Ensures a leak proof seal
- Allows intermittent catheterization with the device in place
- No size/fit issues - one type fits all anatomy
 - Large/Small
 - Circumcised/Uncircumcised
 - Retracted

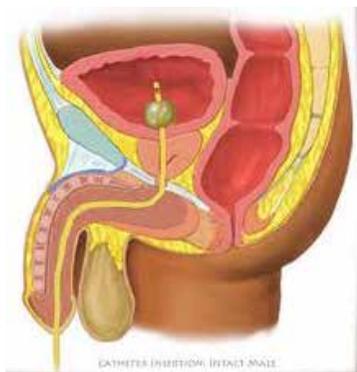
***PATIENT DIGNITY,
QUALITY OF LIFE,
FREEDOM,
CAREGIVER
RELIEF***

Current Standards of Care: Foley

- High UTI rate - 100% infection rate with long term use
- Injury to the shaft of the penis and/or the urinary opening
- Requires skilled nursing staff to insert and maintain
- Foley frequently misused when not medically necessary
- New antimicrobial catheter coatings are ineffective



Source: List 1

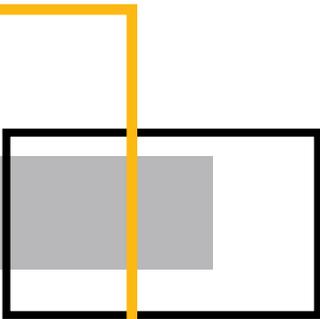




Current Standards of Care: Condom Catheters

- Many sizes/types - all can cause skin inflammation & infections
- Wearing one too tightly can cause reduced blood flow and tissue damage
- Conversely, wearing one too loosely can cause “pop-offs” and leaks.

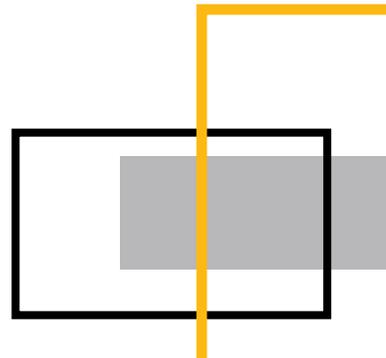
Source: List 2



Current Standards of Care: Pads/Briefs

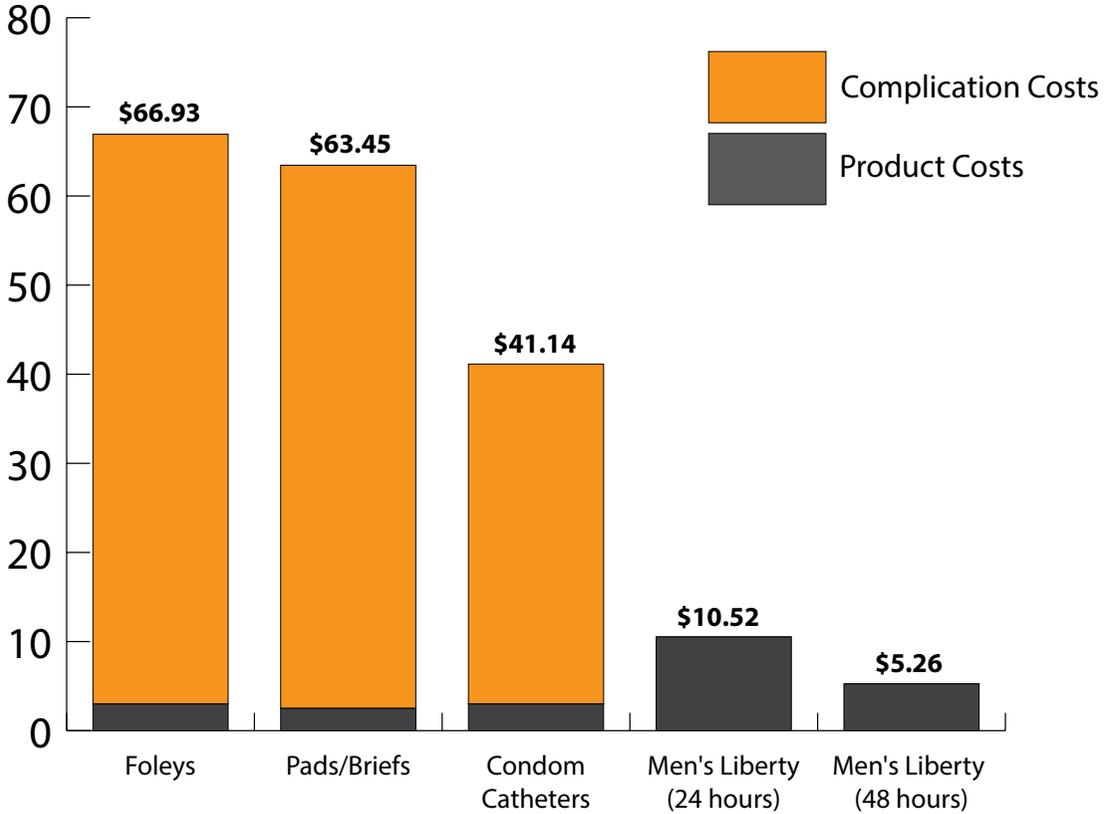
- Sensitive skin soaks in urine
- Frequently causes skin inflammation, sores and ulcers
- Urine smell
- Undermines personal dignity

Source: List 3





Average Cost of Complications (per day)



Men's Liberty can save your patient's time and money.

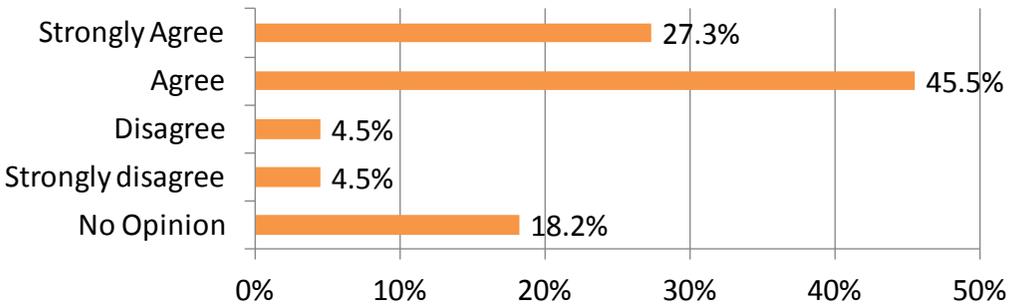


Independent Product Evaluation

Autumn 2012 - Men's Liberty was independently evaluated by a large midwestern hospital chain. An excerpt of the results are below. Additional information on the study is available online at:

www.MensLiberty.com/evaluation

Likely To Advocate for Use of Men's Liberty



Attribute	Men's Liberty	No Preference	Condom Catheter
Easy to apply	59.1%	22.7%	18.2%
Satisfactory urine flow	50.0%	40.9%	9.1%
Stays on securely	45.5%	50.0%	4.5%
No urine leakage	45.5%	40.9%	13.6%
Wear time	40.9%	50.0%	9.1%
Does not cause skin redness/irritation	40.9%	50.0%	9.1%
Patient comfort	36.4%	59.1%	4.5%
Patient acceptance	31.8%	68.2%	0.0%

Patients & RNs prefer Men's Liberty on EVERY attribute evaluated.



What Do Doctors Say About Men's Liberty?

- Health Care Professionals:

“My patient, Mark F., has been using [Men's Liberty] and is very pleased with the performance of this product. He is able to apply one [Men's Liberty] and have it remain in place for 24 hours. He has not had any popping off or leaking with this product. More importantly, he is cleared of the pin-point sore the traditional condom catheters were causing on his penis.”

~ James A. Rohde, M.D.

“Our surgeons in both the Department of Urology and the Department of Otolaryngology have been impressed with the results of Men's Liberty in controlling incontinence post surgically in males without having to utilize condom or indwelling catheters. I think this product's potential for cost saving could be astronomical in treating and caring for the incontinent male.” ~ Timothy C. Mulloy, BSN, RN, CETN, WOCN at the University of Kansas Medical Center

- Caregivers:

“This product has made a large impact on our lives. The most degrading thing that my husband can think of is being in a diaper. Your product helped him to avoid that bit of humiliation. We were able to utilize this product so that he could attend our daughters' graduation in comfort and without the fear of an “accident” that would further embarrass him. This product helped my husband retain his dignity in the face of a terrible disease.”

~T. Porter



What Do Patients Say About Men's Liberty?

- Caregivers continued:

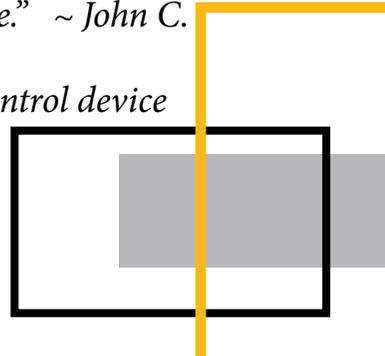
"I don't know how to explain it. It just feels like freedom. I don't have to haul diapers with us everywhere we go. I don't always have to be thinking in the back of my mind where I'm going to change him or how I can make him comfortable." ~ Kathy Hellwig, son has Spastic Quadriplegia Cerebral Palsy

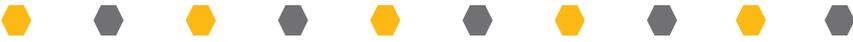
- Patients:

"After many complications with prostate surgery, I was left with complete incontinence. Every day was miserable and I did not want to go anywhere. After my doctor offered the Men's Liberty, life has been much better. I am very thankful there was a product like the Men's Liberty that has given me some normalcy in my life and allowed me to be active again." ~Phil C.

"Men's Liberty has been a lifesaver. Wearing an indwelling catheter is not an optimal solution because of the potential for UTIs. Men's Liberty is not an invasive product, and it has allowed me to maintain my lifestyle with my work and family. It's a wonderful option to have." ~ John C.

"I didn't think there was a bladder control device on the market that would enable me to have the quality of life I have with Men's Liberty. Thank you!" - Glen P.





References

Source List 1:

- Kunin, Calvin M. “Nosocomial Urinary Tract Infections and the Indwelling Catheter: What is New and What is True?” *Chest* 2001; 120: 10-12.
- Centers for Medicare and Medicaid Services (CMS). CMS Manual System Pub. 100-07 State Operations Provider Certification). Transmittal 8. June 28, 2005.
- Munasinghe, Rajika L. MD. Et al. “Appropriateness of Use of Indwelling Urinary Catheters in Patients Admitted to the Medical Service”. *Infection Control and Hospital Epidemiology*. October, 2001. Vol.22 No.10. 647-9
- Sanjay Saint, MD, MPH and Benjamin A. Lipsky, MD. “Preventing Catheter-Related Bacteriuria: Should We? Can We? How?” *Archives of Internal Medicine*. 159 (26 April 1999): 800-808.
- Gokula, Radha, Ramana, Murthy, et al. “Inappropriate use of urinary catheters in elderly patients at a midwestern community teaching hospital”. *American Journal of Infection Control*. June, 2004. 196-9.
- Stringham J., Young N., “Using MedPAR data as a measure of urinary tract infection rates: implications for the Medicare inpatient DRG payment system.” *Perspect Health Inf. Management* 2005 Dec 8;2:12. Available at <http://www.ncbi.nlm.nih.gov/pmc/articles/18066380/?tool=pubmed>. Last accessed May 18, 2011.
- Gould, Carolyn, “Catheter-associated urinary tract infection (CAUTI) toolkit”, Centers for Disease Control and Prevention, Available at http://www.cdc.gov/HAI/pdfs/toolkits/CAUTItoolkit_3_10.pdf. Last accessed: May 18, 2011.
- Calculated from TMIT-APIC Healthcare Associated Infections Cost Calculator. Available online at: http://www.apic.org/Content/NavigationMenu/PracticeGuidance/GuidelinesStandards/Cost_Calculators.htm. Last accessed: May 18, 2011.
- HCUPnet data on all hospital stays in the U.S. 2009, Online at: http://hcupnet.ahrq.gov/HCUPnet.jsp?Id=D3E4AF24057E106B&Form=SelCROSSTAB&JS=Y&Action=%3E%3ENext%3E%3E&_Oneway=Yes. Last accessed: May 18, 2011.

Source List 2:

- TMIT-APIC Healthcare Associated Infections Cost Calculator. Online: http://www.apic.org/Content/NavigationMenu/PracticeGuidance/GuidelinesStandards/Cost_Calculators.htm. Accessed: May 18, 2011.
- Ouslander, J., Greengold, B., Chen, S., “External Condom Catheter Use and Urinary Tract Infections Among Incontinent Male Nursing Home Patients” *Journal of the American Geriatrics Society*, Vol. 35, 1987.



References

- Johnson, Edwin, “The Condom Catheter: Urinary Tract Infections and Other Complications”, *Southern Medical Journal*, 76(5) 579-582, 1983.
- Stickler, D., Zimakoff, J., “Complications of urinary tract infections associated with devices used for long term bladder management,” *Journal of Hospital Infection*, Nov (28(3)), 177-94, 1994.
- Golji, H., “Complications of External Condom Drainage,” *Paraplegia* (19), 1981.
- Stelling, J., RN, MSN, CRR, Hale, P., RN, BSN, CRRN, “Research update: clinically-derived protocol for changing condom catheters in males with spinal cord injury”, Pushin’ On Newsletter, Vol12[1]Winter, 1994. Access online: <http://www.spinalcord.uab.edu/show.asp?durki=21450>. May 19, 2011.
- Perakash, I., Kabalin, J., Lennon, S., Wolfe, V., “Use of penile prostheses to maintain external condom catheter drainage in spinal cord injury patients”, *Paraplegia* 30 (1992) 327-332.
- WOCN Continence Committee 10/08, “WOCN Condom Catheter Fact Sheet” Available online: http://www.wocn.org/pdfs/WOCN_Library/Fact_Sheets/C_EXTCAT.pdf Last Accessed May 19, 2011.

Source List 3:

- Narayanan, S., Van Vleet, J., Strunk, B., Ross, R., Gray, M., “Comparison of Pressure Ulcer Treatments in Long-Term Care Facilities: Clinical Outcomes and Impact on Cost,” *J Wound Ostomy Continence Nurs.*, May/June 2005, pg. 163-170
- Souza, D., Santos, V., “Incidence of Pressure Ulcers in the Institutionalized Elderly” *J Wound Ostomy Continence Nurs.*, 2010;37(3):272-276.
- Junkin, J., Moore-Lisi, G., Selekof, JL. “What we don’t know can hurt us: pilot prevalence survey of incontinence and related perineal skin injury in acute care [abstract]. *Clinical Symposium on Advances in Wound Care*; 2005 Oct 23-26; Las Vegas (NV)
- BorrieMJ, Davidson HA. Incontinence in institutions: costs and contributing factors. *CMAJ* 1992; 147 (3): 322-8
- BoyingtonJE, Howard DL, Carter-Edwards L, et al. Differences in resident characteristics and prevalence of urinary incontinence in nursing homes in the southeastern United States. *NursRes* 2007; 56 (2): 97-107
- AlyR, Shirley C, CunicoB, et al. “Effect of prolonged occlusion on the microbial flora, pH, carbon dioxide and trans-epidermalwater loss on human skin.” *J Invest Dermatol* 1978; 71 (6): 378-81

References

- Keller, PA., Sinkovic, SP., Miles, SJ., “Skin dryness: a major factor in reducing incontinence dermatitis.” *Ostomy Wound Manage* 1990; 30: 60-4
- Gray, M., “Optimal Management of Incontinence-associated Dermatitis in the Elderly”, *Am J Clin Dermatol* 2010; 00 (0)
- Foureur, N., Vanzo, B., Meaume S., et al. Prospective etiological study of diaper dermatitis in the elderly.” *Br J Dermatol* 2006; 155 (5): 941-6
- Cuddigan, J., Ayello, EA., Sussman, C., Baranoski, S., eds. “Pressure Ulcers in America: Prevalence, Incidence, and Implications for the Future.” Reston, Va: National Pressure Ulcer Advisory Panel; 2001.
- Graves N., Birrell, F., Whitby, M., “Effect of pressure ulcers on length of hospital stay.” *Infect Control Hosp Epidemiol.* 2005;26:293
- Voss, A. C., Bender, S. A., Ferguson, M. L., Sauer, A. C., Bennett, R. G. and Hahn, P. W. (2005), “Long-Term Care Liability for Pressure Ulcers.” *Journal of the American Geriatrics Society*, 53:1587–1592.
- M G Kemp et al, “Factors that contribute to pressure sores in surgical patients,” *Research in Nursing & Health* 13 (October 1990)293-301; C Vermillion, “Operating room acquired pressure ulcers,” *Decubitus*3 (February 1990) 26-30; V D Wagner, “Intraoperativelyacquired pressure ulcers,” *Today’s OR Nurse* (January/February 1994) 18-21; L Marchette, I Arnell, E Redick, “Skin ulcers of elderly surgical patients in critical care units,” *Dimensions of Critical Care Nursing* 10 (November/December 1991) 321-329; V M Hoshowsky, C A Schramm, “Intraoperativepressure sore prevention: An analysis of bedding materials,” *Research in Nursing & Health* 17 (October 1994) 333-339; M Versluysen, “How elderly patients with femoral fracture develop pressure sores in hospital,” *British Medical Journal* 292 (May 17, 1986) 1311-1313; C T Papantonio, J M Wallop, K B Kolodner, “Sacral ulcers following cardiac surgery: Incidence and risks,” *Advances in Wound Care* 7 (March 1994) 24-36.
- Reddy, M., Sudeep, G., Rochon, P., “Preventing Pressure Ulcers: A Systematic Review”, *JAMA*, 2006;296:974-984.
- Farage, M. A., Miller, K. W., Berardesca, E. and Maibach, H. I. (2007), “Incontinence in the aged: contact dermatitis and other cutaneousconsequences.” *Contact Dermatitis*, 57: 211–217.

Proud Sponsor of:



Refer Your Patients

Men's Liberty is covered by: Medicare Part B (HCPCS: A4326), most state Medicaid, VA/TriCare, most private insurance plans and workers compensation.

In order to get reimbursed, the physician must provide a **Letter of Medical Necessity (LMN)** and a **Progress Note (PN)**.

Letter of Medical Necessity – Men's Liberty™ by BioDerm

Patient Name: _____
 SSN #: _____ Date of Birth: _____
 Shipping Address: _____
 City: _____ State: _____ Zip: _____ Phone(home) _____

Effective Dates:

Medicare (Part B): ____ / ____ / ____ Medicaid: ____ / ____ / ____
 Medicare #: _____ Medicaid #: _____

Complete for HMO, Private Insurance and Worker's Compensation:

Insurance Company: _____ Phone: _____
 Policy Holder's Name: _____
 SSN #: _____ Date of Birth: _____

Type of Policy:

Major Medical PPO HMO Worker's Compensation Other

Patient Relationship to Policy Holder:

Self Spouse Child Other

ID #: _____ Group #: _____

Employer: _____

Special Usage Notes:

Medical Information to be Completed by Physician

I certify the medical necessity of BioDerm's Liberty3.0 as the required therapy for this patient. All other, less expensive means of collecting urine from this patient are not successful for the patient to maintain health. I am ordering this product for the patient as a reasonable and necessary treatment for his diagnosis.

The Patient experiences the following type of urinary incontinence (check all that apply):

Nocturnal Enuresis (ICD-9 code 788.36) Continuous Leakage (ICD-9 code 788.37)
 Urge Incontinence (ICD-9 code 788.31) Mixed Incontinence (ICD-9 code 788.33)
 Post Void Dribbling (ICD-9 code 788.35) Stress Incontinence Male (ICD-9 code 788.32)
 Urinary Incontinence (ICD-9 code 788.30) Other Urinary Incontinence (ICD-9 code 788.39)

Additional health complication(s) relating to patient's urinary dysfunction (check all that apply):

Cerebral Palsy (ICD-9 code 343.9) Muscular Dystrophy (ICD-9 code 359.0)
 Spina Bifida (ICD-9 code 741.0) Quadriplegia (ICD-9 code 344.0)
 Multiple Sclerosis (ICD-9 code 340.0) Paraplegia (ICD-9 code 344.10)
 ALS (ICD-9 code 335.2) Other: _____ ICD-9 code: _____

The Patient's urinary incontinence is a result of the following condition (check all that apply):

Urinary Tract Injury (ICD-9 code 599.0) Decubitus Ulcers (ICD-9 code 707.0)
 Penile Shaft Wound (ICD-9 code 878.0) Penile Ulcer (ICD-9 code 607.89)
 Urinary Tract Infection (ICD-9 code 98.00) Other: _____ ICD-9 code: _____

As a result of insufficient urinary incontinence management, the patient's health is: _____

SAMPLE LMN ONLY.
 TO RECIEVE FULL LMN CONTACT OUR CUSTOMER CARE TEAM.

We must also receive a **Progress Note** that states why the patient is not a candidate for the least costly alternative. Some common examples are:

- The patient is not a candidate for condom catheters due to retracted or small anatomy.
- The patient is not a candidate for condom catheters due to leakage/persistent moisture.



Contact Us

If you have any questions, would like more information or to receive a sample of the product, please contact our Customer Care Team or visit us online to submit a request form.

Men's Liberty

12320 73rd Court North
Largo, FL 33773

Customer Service:

(800) 814-3174

CustomerCare@MensLiberty.com

Check Out The Men's Liberty Blog!

We are hosting a new incontinence blog with excellent information, news and research on incontinence, related diagnoses and caregiving. We welcome guest blogs from physicians and other health care professionals.

Visit Us Online for More Information at:
www.MensLiberty.com

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