Washington State Health Care Authority

Negative pressure wound therapy

Clinical Expert

Terence M. Quigley

Chief, Division of Surgery
Northwest Hospital and Medical Center

Vascular and Endovascular Surgery
Seattle Pacific Surgeons

Clinical Associate Professor of Surgery
University of Washington

Adjunct Clinical Assistant Professor of Surgery
Uniformed Services University of the Health Sciences, Bethesda, Maryland

WA - Health Technology Assessment

Applicant Name	Terence M Quigley
Address	1560 N 115th Street
	Suite 102
	Seattle, WA 98133

1. Business Activities

(a) If you or a member of your household was ***an officer or director of a business*** during the immediately preceding calendar year and the current year to date, provide the following:

Title	Business Name & Address	Business Type
Chief of Surgery	Northwest Hospital 1550 N115th Street Seattle, WA 98133	Hospital
Trustee	Pacific Vascular, Inc 11714 N Creek Pkwy N #100 Bothell, WA 98011	Ultrasound Services
Click here to enter text.	Click here to enter text.	Click here to enter text.

(b) If you or a member of your household ***did business under an assumed business name*** during the immediately preceding calendar year or the current year to date, provide the following information:

Business Name	Business Address	Business Type
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

2. Honorarium

If you ***received an honorarium of more than $100*** during the immediately preceding calendar year and the current year to date, list all such honoraria:

Received From	Organization Address	Service Performed
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

3. Sources of Income

(a) Identify ***income source(s) that contributed 10% or more of the combined total gross household income*** received by you or a member of your household during the immediately preceding calendar year and the current year to date.

Source Name & Address	Received By	Source Type
Northwest Hospital Seattle, WA	Terence Quigley	Hospital/employer

Pacific Vascular, Inc. Bothell, WA	Terence Quigley	Ultrasound services
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

(b) Does any income source listed above relate to, or could it reasonably be expected to relate to, business that has, or may, come before the Committee?

☒ Yes ☐ No

If "yes", describe: Click here to enter text.
Northwest Hospital and UW Medicine utilize healthcare technology and receive funds from the State of Washington
Click here to enter text.

(c) Does an income source listed above have a legislative or administrative interest in the business of the Committee?

☒ Yes ☐ No

If "yes", describe: The hospital has numerous legislative intersts
Click here to enter text.
Click here to enter text.

4. Business Shared With a Lobbyist

If you or a member of your household ***shared a partnership, joint venture, or similar substantial economic relationship with a paid lobbyist***, were employed by, or employed, a paid lobbyist during please list the following:

(Owning stock in a publicly traded company in which the lobbyist also owns stock is not a relationship which requires disclosure.)

Lobbyist Name	Business Name	Type Business Shared
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

Provide the information requested in Items 5, 6, and 7 below only if:
(a) Your response involves an individual or business if you or a member of your household did business with, or reasonably could be expected to relate to business that has or may come before the Health Technology Clinical Committee.
(b) The information requested involves an individual or business with a legislative or administrative interest in the Committee.

5. Income of More Than $1,000

List each source (***not amounts***) of income over $1,000, other than a source listed under question 3 above, which you or a member of your household received during the immediately preceding calendar year and the current year to date:

Income Source	Address	Description of Income Source
Approx 6 attorney/ Law offices/Insurance Co		For medical review of pending litigation
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

6. Business Investments of More Than $1,000

(Do not list the amount of the investment or include individual items held in a mutual fund or blind trust, a time or demand deposit in a financial institution, shares in a credit union, or the cash surrender value of life insurance.)

If you or a member of your household had a personal, beneficial interest or investment in a business during the immediate preceding calendar year of more than $1,000, list the following:

Business Name	Business Address	Description of Business
Only common shares of exchange listed companies	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

7. Service Fee of More Than $1,000

(Do not list fees if you are prohibited from doing so by law or professional ethics.)

List each ***person for whom you performed a service for a fee of more than $1,000*** in the immediate preceding calendar year or the current year to date.

Name	Description of Service
Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.

I certify that I have read and understand this Conflict of Interest Form and the information I have provided is true and correct as of this date.

Print Name Terence M Quigley

Check One: ☐ Committee Member ☐ Subgroup Member ☒ Contractor

WA - Health Technology Assessment

[redacted] 9-23-2016

Signature Date

CURRICULUM VITAE

TERENCE MICHAEL QUIGLEY, MD

CURRENT POSITIONS:

Chief, Division of Surgery
Northwest Hospital and Medical Center
Seattle, Washington

Vascular and Endovascular Surgery
Seattle Pacific Surgeons
Seattle, Washington

Clinical Associate Professor of Surgery
University of Washington
Seattle, Washington

Adjunct Clinical Assistant Professor of Surgery
Uniformed Services University of the Health Sciences
Bethesda, Maryland

ADDRESS:

Office: 1560 North 115th Street, Suite 102
Seattle, WA 98133
Tel: 206-368-1070
Fax: 206-363-4172
E-mail: tquigley@nwhsea.org

Home: [redacted]

PERSONAL DATA:

Date of Birth:	April 2, 1952
Place of Birth:	Hempstead, New York, USA
Married:	Wife – Tracy Q. Quigley
Citizenship:	USA

EDUCATION

Boston University, Boston, MA 9/1970 - 9/1973
Major: Medical Science; Degree: BA (cum laude)

Boston University, Boston, MA 9/1972 - 5/1976
Major: Medicine; Degree: MD

RESIDENCY, FELLOWSHIP

University of Minnesota Hospital, Minneapolis, MN 6/1976 - 6/1983
Resident, Surgery
Chief Resident, Surgery (1982 – 1983)

University of California, San Francisco, CA 7/1984 - 6/1985
Fellow, Vascular Surgery
Instructor, Department of Surgery

RESEARCH TRAINING

University of Minnesota, Minneapolis, MN 1979 - 1981
NIH Fellow, Surgery/Physiology

HONORS/AWARDS

Health Professions Scholarship (Air Force)	1973 - 1976
National Research Service Award (NIH)	1979 - 1981
Appointed -- Military Consultant in Vascular Surgery to the Surgeon General	1987
Air Force Meritorious Service Medal	1988
Joel Baker Surgical Resident Teaching Award	1989
Virginia Mason Housestaff Teaching Award	1989, 1991
Seattle Magazine – Seattle's Best Doctors	2000 – 2011 (n/c)
Best Doctors in America	2001 – 2011 (n/c)
Champion of Justice Award, King County Bar Association	2002
Consumer's Checkbook "Top Doctors"	2004

MILITARY SERVICE

United States Air Force		1973 - 1988
Active Duty		1983 - 1988
Lt. Colonel, Medical Corps	Honorable Discharge:	October 1988

CERTIFICATIONS

National Board of Medical Examiners, Diplomat, #171348	1977
American Board of Surgery, Diplomat, #29345	1984
Recertification:	2004
Recertification:	2014
American Board of Surgery, Certificate of Special Qualifications in Vascular Surgery, Diplomat, #100072	1989
Recertification:	2009
Recertification:	2019

Certified, Advanced Trauma Life Support, Instructor	1985 - 2001
Re-certified, Basic Life Support	2004
Registered Physician in Vascular Interpretation	2005 -Present

PROFESSIONAL LICENSURES

Medical License, Minnesota (inactive)	#023628-5	1977 - 1987
Medical License, New Mexico (inactive)	#83-276	1983 - 1984
Medical License, California (inactive)	#G-52376	1984 - 1986
Medical License, Washington	#0025499	1988 - Present

SOCIETY MEMBERSHIPS

Surgical Associate, Uniformed Services University	1984 - Present
Association for Academic Surgery	1985 - 2002
Association of Military Vascular Surgeons	1985 - 88
Chesapeake Vascular Society	1985 - 88
Corresponding Member	1989 - Present
Peripheral Vascular Surgery Society	1987 - Present
Local Arrangements Chairman, Annual Meeting	1994
Program Committee	1994
Puget Sound Vascular Society	1988 - Present
Co-Chair	1992 - 2002
American College of Surgeons, Fellow	1988 - Present
Fellow, Washington State Chapter	1989 - Present
Councilor	1995 - 1997
Membership Committee Chair	1998 - 1999
President, Washington Chapter	2000
Governor, Washington State	2002 – 2008
Socioeconomic Committee	2004 -- 2008
Pacific Northwest Vascular Society	1989 - Present
Secretary-Treasurer	1994 - 1997
President	1999
King County Medical Society	1989 - Present
Trustee	1997, 1998
Secretary-Treasurer	1999
Alternate Delegate to WSMA	1995, 1996
Delegate to WSMA	1997- 2011
President	2001
Judicial Council	2002 - Present
Washington State Medical Association	1989 - Present
Trustee	1999 – 2007
Alternate Delegate, AMA	2007 - 2008
American Association for Vascular Surgery	1991 – 2003
Society for Vascular Surgery	2003 - Present
North Pacific Surgical Association	1992 - Present
Seattle Surgical Society	1992 - Present
Program Chairman	1995, 1996
Secretary-Treasurer-Elect	1998, 1999
Secretary-Treasurer	2000, 2001
President	2003
American Medical Association	1992 - Present
Western Vascular Society	1994 - Present
Program Committee	1999
Secretary-Treasurer	1999 - 2000
Treasurer	2000 - 2002
Pacific Coast Surgical Association	1994 - Present
American College of Physician Executives	1995 – 2002
Society for Vascular Ultrasound	2003 – Present

HOSPITAL APPOINTMENTS / PRINCIPAL POSITIONS HELD

University of Minnesota, Minneapolis, MN 1982-1983
Chief Resident, Surgery

USAF Hospital Cannon, Cannon AFB, NM 1983-1984
Assistant Chief, Surgery

University of California, San Francisco, CA 1984-1985
Clinical Instructor, Surgery
Fellow -- Vascular Surgery

Malcolm Grow USAF Medical Center 1985-1988
Andrews AFB, Maryland

Chief, Vascular Surgery
Assistant Chief, General Surgery
Surgical Director, Intensive Care Unit
Director of Quality Assurance, Dept. of Surgery
Director, Surg. Physician Asst. Training Program

Uniformed Services, University of the Health Sciences
Bethesda, Maryland

Assistant Professor, Surgery 1985 - 1988

Uniformed Services University of the Health Sciences
Bethesda, Maryland

Clinical Assistant Professor, Surgery 1988 - Present

University of Washington, Seattle, WA
Clinical Assistant Professor, Surgery 1989 - 1997
Clinical Associate Professor, Surgery 1998 – Present

Virginia Mason Medical Center, Seattle, WA	
Attending Staff, Section of General, Thoracic, & Vascular Surgery	1988 - 2002
Director, Noninvasive Vascular Laboratory	1991 - 1998
Head, Section of General, Thoracic, & Vascular Surgery	1992 - 2002
Deputy Chief of Surgery	1993 - 2002
Associate Program Director, General Surgical Training Program	1994 - 2002
Acting Chief of Surgery	1998 – 1999
Courtesy Staff	2002 -- 2005
Swedish Hospital Medical Center, Seattle, WA	1998 – Present
Courtesy Privileges	
Northwest Hospital, Seattle, WA	1998 - Present
Deputy Chief, Surgery	2003 – 2006
Chief, Division of Surgery	2006 – Present
Director, Surgical Services	2007 - Present
Chairman, Vascular Audit	2002 – 2005
Chairman, Surgery Audit	2006 – Present
NWH Executive Committee	2006 – Present
Governance	
Credentials	
Process Improvement and Safety	
Director, Northwest Hospital Wound Care and Hyperbaric Oxygen Center	2009 - Present
Stevens Hospital, Edmonds, WA	2006 – Present
Courtesy Privileges	
Proliance Surgeons Inc., PS	2002 – 2010
Board of Directors	2004 – 2007
Treasurer	2006 -- 2007
MDIC / MDRRG Insurance	2004 – 2007
Board of Directors	2004 – 2007
Secretary	2004 – 2007
Pacific Vascular, Inc, Bothell, WA	2002 – Present
Associate Physician, duplex examination interpretation	
Faculty, CME Division (CompVue)	
Board of Directors	2008 -- Present

ADMINISTRATION/COMMITTEE ACTIVITIES

USAF Hospital Cannon, Cannon AFB, New Mexico	1983 – 1984
Quality Assurance Committee	
Medical Records Committee	
Malcolm Grow USAF Medical Center, Andrews AFB	1985 – 1988
Quality Assurance Committee, Surgery Director	
Critical Care Committee	
Director, Surg. Physician Assistant Training Program	
Director, Noninvasive Vascular Lab	
Virginia Mason Medical Center, Seattle, WA	
Public Affairs Committee	1988-2002
Chair	1998-2002
Quality Assessment Committee	1988-2002
(VM Continuing Quality Improvement Committee)	
Virginia Mason CQI Guidance Team	1991-1995
Educational Policy Committee	1989-1999
Physician Compensation Committee	1991-2000
Chairman	1995-1999
Critical Care Committee	1992-1999
Marketing Committee	1993-2002
Perioperative Services Committee	1995-2002
VM/GH Med/Surg SHIST Subcommittee, Ad Hoc	1996
Physician Co-Chair	
Sand Point Country Club	1991 – Present
Green Committee	2003 – 2006
Handicap Committee	2003 – 2008
Chair	2004 – 2008

MANAGEMENT CONTINUING MEDICAL EDUCATION

American College of Physician Executives	
Physicians in Management, Course 1	March 1998
Physicians in Management, Course 2	Sept. 1998
Financial Decision Making	March 1999
Advanced Leadership Strategies for Healthcare Executives	
Harvard School of Public Health	Nov. 1999
Leadership Development Program (Virginia Mason)	Apr, Sept, Oct 2001

TEACHING, FORMAL

Course	Contribution	Hrs	Year
Surgery Study	Lecture	4	1981-83
University of Minn.			
Intro to Clin Med	Lecture/Demo	12	1984-85
U Cal SF			
Stud Clerkship Lect	Lecture	20	1985-88
USUHS	OEM Course	20	
	Lecture	4	1986-88
Law Medicine	Lecture	4	1986-88
MGMC			
Emer Med Course	Lectures	24	1986-88
MGMC			
ATLS Courses (x3/yr)	Lecture/Demo	60	1985-88
USUHS/C4			
Resident Conf	Lecture	10	1988-2002
VM Hospital			
Vascular Conf	Lecture	40	1988-2002
VM Hospital			
Vascular Staff Rounds	Teaching	150	1989-2002
Advanced Trauma	Lecture/Demo		1986-2001
Life Support	1 course/yr		1990-1998
Vascular Interpretation	3 courses/yr	3	2004- Present
Vascular conference moderator	monthly	2	2006 - present

PUBLICATIONS

A. JOURNAL ARTICLES

1. Quigley TM, Magallanes F, Bonsack ME, Delaney JP. Effect of hypothyroidism on antral G-cells and serum gastrin in the rat. Gastroenterology 78:1240, 1980.
2. Quigley TM, Magallanes F, Bonsack ME, Eisenberg MM, Delaney JP. Effects of hypothyroidism on G-cell population. Surg Forum 31:164-65, 1980.
3. Magallanes F, Quigley TM, Bonsack ME, Delaney JP. The relationship of lumenal pH and distention to antral G-cell numbers. J Surg Res 30:349-53, 1981.
4. Magallanes F, Quigley TM, Bonsack ME, Eisenberg MM, Delaney JP. Antral proliferation of G-cells after truncal, parietal cell, and antral vagotomy. Gastroenterology 80(5):1221, 1981.
5. Magallanes F, Quigley TM, Mulholland MW, Bonsack ME, Delaney JP. Antral proliferation of G-cells after truncal, parietal cell, and antral vagotomy. J Surg Res 32:377-81, 1982.
6. Magallanes F, Mulholland MW, Quigley TM, Bonsack ME, Delaney JP. Does a non-acid lumen cause antral G-cell hyperplasia? Gastroenterology 82(5):1256, 1982.
7. Quigley TM, Sutherland DER, Howard RJ. Use of Hickman and Broviac catheters in high risk patients. Minn Med 65(2):87-90, 1982.
8. Mulholland MW, Magallanes F, Quigley TM, Delaney JP. In-continuity gastrointestinal stapling. Dis Colon Rectum 26:586-89, 1983.
9. Mulholland MW, Quigley TM, Bonsack ME, Delaney JP. Relationship of antral gastrin cells and serum gastrin to thyroid function in the rat. Endocrinology 114(3):840-844, 1984.
10. Quigley TM, Stoney RJ. Post-laminectomy arteriovenous fistulae: the anatomy defined. J Vasc Surg 2(6):828-33, 1985.
11. Quigley TM. Renal artery aneurysm: treatment by ex-vivo repair. Virginia Mason Bulletin, Spring 1991.
12. Craven J, Quigley TM, Bolen J, Raker EJ. Current management and clinical outcome of hemangiopericytomas. Am J Surg 163(5):490-93, 1992.
13. Quigley TM. Renovascular disease: guidelines for intervention. Virginia Mason Bulletin, Spring 1993.
14. Casey KM, Quigley TM, Kozarek R, Raker EJ. Lethal nature of ischemic gastropathy. Am J Surg 165(5):683, 1993.
15. Rose SC, Quigley TM, Raker EJ. Revascularization for chronic mesenteric ischemia: comparison of operative arterial bypass grafting and percutaneous transluminal angioplasty. J Vasc Interventional Radiol 6(3):339-349, 1995.
16. Executive Committee for ACAS. Endarterectomy for asymptomatic carotid artery stenosis. JAMA 273(18):1421, 1995.
17. Thirlby RC, Quigley TM, Anderson RP. The shift toward a managed care environment in a multispecialty group practice model. Arch Surg 131:1027, 1996.
18. Zimmer P, Quigley TM, Raker EJ. Hypogastric artery aneurysm. Ann Vasc Surg 13(5):545-549, 1999.
19. Quigley TM, Ryan WR, Morgan SM. Patient satisfaction and outcomes following carotid endarterectomy using a selective policy of local anesthesia. Am J Surg 179:382-385, 2000

20. Finch, L, Heathcock, BR, Quigley, T, Jiranek, G, Robinson, D. Emergent Treatment of a Primary Aortoenteric Fistula with N-butyl 2-cyanoacrylate and Endovascular Stent. J Vasc Intervent Rad 13:841-843, 2002.
21. Hansman, MF, Neuzil, D, Quigley, TM, Hauptmann, E, Fotoohi, M, Robinson, D, Raker, EJ. A Comparison of 50 Initial Endoluminal Endograft Repairs for Abdominal Aortic Aneurysm With 50 Concurrent Open Repairs. Am J Surg 185(5): 441-444. 2003.

A. BOOK CHAPTERS, MONOGRAPHS

1. Delaney JP, Dressel TD, Quigley TM. Stomal gastritis. In: *Gastrointestinal Surgery*. Symposium Specialists, Miami, FL, 1979, pp 187-94.
2. Delaney JP, Quigley TM. Gastroesophageal devascularization for bleeding varices. In: *Hepatic, Biliary and Pancreatic Surgery*. Symposium Specialists, Miami, FL, 1980, pp 705-13.
3. Delaney JP, Quigley TM. Endocrine emergencies. In: *Emergency Surgery*. Year Book Medical Publishers, Chicago, 1982.
4. Quigley TM, Goldstone J. Occlusive disease of the upper extremity. In: *Current Surgical Therapy 1985-1986*. CV Mosby Co., St. Louis, 1985.
5. Quigley TM, Goldstone J. Venous stasis dermatitis and ulcers. In: *Current Emergency Therapy 1986*. Aspen Systems Corp., 1985.
6. Quigley TM. Endocrine emergencies. In: *Manual of Critical Care*. CV Mosby Co., St. Louis, 1986.
7. Quigley TM, Stoney RJ. Ruptured abdominal aortic aneurysms. In: *Difficult Problems in General Surgery*. CV Mosby Co., St. Louis, 1988.
8. Quigley TM, Stoney RJ. Extra-anatomic bypass: a new look (opposing view). In: *Advances in Surgery* (Vol. 26). J. Cameron, (ed), CV Mosby Co., St. Louis, 1993.
9. Quigley TM. Venous disease: an overview. In: *Audio Digest* (Internal Medicine) (Vol. 40:2), January 1993.

A. ABSTRACTS, LETTERS, PUBLISHED DISCUSSIONS

1. Delaney JP, Magallanes F, Quigley TM, Bonsack ME, Eisenberg MM. Distention, alkalinization and antral G-cell hyperplasia. Regulatory Peptides 1:s24, 1980.
2. Quigley TM. Discussion: Chen JC, et al. Predictors of death in non-ruptured and ruptured abdominal aortic aneurysms. J Vasc Surg 24(4):614, 1996.
3. Quigley TM. Elections. Bulletin, King County Medical Society, Vol 80, 1, Jan-Feb 2001.
4. Quigley TM. Legislative Action. Bulletin, King County Medical Society, Vol 80, 2, Feb-Mar 2001.
5. Quigley TM. Perspective. Bulletin, King County Medical Society, Vol 80, 3, Mar-Apr 2001.
6. Quigley TM. My Nursing Education. Bulletin King County Medical Society, Vol 80, 4, Apr-May 2001.
7. Quigley TM. Communication. Bulletin, King County Medical Society, Vol 80, 5, May-June 2001.
8. Quigley TM. Learning. Bulletin, King County Medical Society, Vol 80, 6, Jun-Jul 2001.

9. Quigley TM. Illegal Drug Policy. Bulletin, King County Medical Society, Vol 80, 7, Jul-Aug 2001.
10. Quigley TM. Medicine and the Media. Bulletin, King County Medical Society, Vol 80, 8, Aug-Sep 2001.
11. Quigley TM. Opinion. Bulletin, King County Medical Society, Vol 80, 9, Sep-Oct 2001.
12. Quigley TM. End of Life Issues. Bulletin, King County Medical Society, Vol 80, 10, Nov-Dec 2001.
13. Quigley TM. Thank you. Bulletin, King County Medical Society, Vol 80, 11, Dec-Jan 2002.

UNPUBLISHED WORK/SCIENTIFIC PRESENTATIONS

International/National/Regional :

Presentation: "Distention, Alkalinization and G-cell Hyperplasia." Third International Symposium on Gastrointestinal Hormones, Cambridge, UK. Sept. 1980.

Presentation: "Effects of Hypothyroidism on G-cell Population." American College of Surgeons, Surgical Forum, Atlanta, GA. Oct. 1980.

Presentation: "The Importance of Distention and Luminal pH on Antral G-cell Numbers." Annual Meeting, Association of Academic Surgery, Birmingham, AL. Nov. 1980. (Magallanes)

Presentation: "Effect of Hypothyroidism on Antral G-Cells and Serum Gastrin in the Rat." Annual Meeting, American Gastroenterological Association, Salt Lake City, UT, 1981.

Presentation: "Arteriovenous Fistulae Following Lumbar Laminectomy -- The Anatomy Defined." Annual Meeting, Southern Association for Vascular Surgery, West Palm Beach, FL, Jan. 1985.

Presentation: "Thoracic Outlet Syndrome: Controversies." Annual Meeting, Military Vascular Surgery Society, Bethesda, MD. Dec. 1986.

Presentation: "Recent Experience in Vascular Reconstruction of the Occluded Infrarenal Aorta. Annual Meeting, Society of Air Force Clinical Surgeons, Oakland, CA. April 1988.

Presentation: "Infrarenal Aortic Occlusion: Options for Reconstruction." Annual Meeting, Peripheral Vascular Society, New York, NY. June 1989.

Presentation: "Traumatic Transection of PTFE Axillofemoral Graft." Annual Meeting, Pacific Northwest Vascular Society. Portland, OR. Nov. 7, 1991. (Gill)

Presentation: "Hemangiopericytoma: Current Management and Clinical Outcome." Annual Meeting, North Pacific Surgical Association, Portland, OR. Nov. 8, 1991. (Craven)

Presentation: "Isolated Hypogastric Artery Aneurysms: A Review." Annual Meeting, Pacific Northwest Vascular Society, Tacoma, WA. Nov. 12, 1992. (Tesnohlidek)

Presentation: "Ischemic Gastropathy: A Lethal Variation of the Ischemic Mesenteric Syndrome." Annual Meeting, North Pacific Surgical Association, Tacoma, WA. Nov. 14, 1992.

Presentation: "Renovascular Reconstruction." University College, Cork, Ireland. Sept. 26, 1994.

Presentation: "Patient Satisfaction and Outcome Following Carotid Endarterectomy Using a Selective Policy of Local Anesthesia." Annual Meeting, Pacific Northwest Vascular Society, Tacoma, WA. Nov. 12, 1998.

Presentation: "Hyperperfusion Syndrome Following Carotid Endarterectomy." Annual Meeting, Pacific Northwest Vascular Society, Tacoma, WA, Nov. 12, 1998. (Miller)

Presentation "Patient Satisfaction and Outcome Following Carotid Endarterectomy." Annual Meeting, North Pacific Surgical Association, Vancouver, B.C., Nov 1999.

Presentation "State of the State - Surgical Socioeconomics." Presidential Address, Annual Meeting Washington Chapter, American College of Surgeons, Skamania, Washington, June 2001.

Presentation "The Diabetic Foot." Science Innovation Synergy 2006. Bellevue, WA, July, 2006.

State/Local:

Presentation: "Surgical Problems During Pregnancy." Surgical Grand Rounds, University of Minnesota, Minneapolis, MN. May 1983.

Presentation: "Arteriovenous Fistula Following Laminectomy." Surgical Grand Rounds, University of California San Francisco, San Francisco, CA. April 1985.

Presentation: "Arteriovenous Fistula Following Laminectomy." Annual Meeting, Northern California Vascular Society, San Francisco, CA. May 1985.

Presentation/ Panelist: "Carotid Artery Surgery." Consortium for Continuing Medical Education, Northern Virginia, *Stroke Update*. Alexandria, VA, 1986.

Presentation: "Surgery for Renovascular Hypertension." Advances in Therapy for Hypertension (Symposium). Virginia Mason Medical Center, Seattle, WA. Feb. 3, 1989.

Presentation: "The Case for Angiography Prior to Carotid Endarterectomy." Annual Meeting, Seattle Surgical Society. Jan. 20, 1990.

Presentation: "Overview of Venous Disease." Vascular Surgery Update 1990. Virginia Mason Medical Center, Seattle, WA. Feb. 2, 1990.

Presentation: "Inactive Treatment Options in Renovascular Disease." Vascular Surgery Update 1990. Virginia Mason Medical Center, Seattle, WA. Feb. 2, 1990.

Presentation: "Noninvasive Vascular Diagnosis: An Overview." Vascular Surgery Update 1990. Virginia Mason Medical Center, Seattle, WA. Feb. 2, 1990.

Presentation: "How to Maximize the Life Expectancy of Right Atrial Catheters: An Algorithm for Success." Annual Meeting, Washington State Chapter, American College of Surgeons, Semiahmoo, WA. June 13, 1990. (Tesnohlidek)

Presentation: "Vascular Complications of Acute Ulcerative Colitis." Annual Meeting, Washington State Chapter, American College of Surgeons, Semiahmoo, WA. June 13, 1990. (McBee)

Presentation: "CT-Guided Percutaneous Drainage of a Periaortic Graft Abscess." Annual Meeting, Washington State Chapter, American College of Surgeons, Semiahmoo, WA. June 13, 1990. (Douglas)

Presentation: "Central Venous Catheters: An Algorithm for Success." Grand Rounds, Virginia Mason Medical Center. Oct. 1990.

Presentation: "Surgical Treatment of Carotid Artery Stenosis." Satellite Symposium, Virginia Mason Medical Center. Oct. 17, 1990.

Presentation: "Physician Attitudes and Responses to Continuous Quality Improvement." Health Services Consortium Annual Leadership Conference, Silverdale, WA. March 15, 1991.

Presentation: "Popliteal Artery Entrapment Syndrome: A Noninvasive Diagnostic Approach." Annual Meeting, Washington State Chapter, American College of Surgeons, Warm Springs, OR. June 16, 1991. (Kowitz)

Presentation: "Extra-Adrenal Pheochromocytoma: A Review." Annual Meeting, Washington State Chapter, American College of Surgeons, Warm Springs, OR. June 16, 1991. (Goodwin)

Presentation: "Revascularization of the Solitary Functioning Kidney." Annual Meeting, Washington State Chapter, American College of Surgeons, Warm Springs, OR. June 16, 1991. (Ebisu)

Presentation: "Endovascular Procedures and Surgeons." Annual Meeting, Washington State Chapter, American College of Surgeons, Warm Springs, OR. June 16, 1991.

Presentation: "Hemangiopericytoma: The Virginia Mason Experience." Annual Meeting, Washington State Chapter, American College of Surgeons, Warm Springs, OR. June 16, 1991. (Craven)

Presentation: "Option of Treatment in Carotid Artery Disease." Staff Meeting, Snoqualmie Hospital. Oct. 3, 1991.

Presentation: "Central Venous Catheters -- When Does the Clot Appear?" Annual Meeting, Seattle Surgical Society, Seattle, WA. Jan. 17, 1992. (Gill)

Presentation: "Renal Artery Reconstruction 1992." Department of Surgery Grand Rounds, University of Washington, Seattle, WA. Jan. 1992.

Presentation: "Common Vascular Problems Causing Cold Hands and Cold Feet."

Staff Conference:

Jefferson County Hospital. Jan. 8, 1992.

Sequim Physicians. Jan. 21, 1992.

Valley General Hospital. Feb. 10, 1992.

Olympic Memorial Hospital. Feb. 10, 1992.

Cascade Hospital. May 5, 1992.

Enumclaw Hospital. Mar. 17, 1992.

Arlington Hospital. Aug. 11, 1992

Presentation: "Venous Disease: Primary Care Perspective." Vascular Surgery for Primary Care Providers, Seattle, WA. May 8, 1992.

Presentation: "Renal Artery Stenosis: When to Investigate." Vascular Surgery for Primary Care Providers, Seattle, WA. May 8, 1992.

Presentation: "Cold Hands, Cold Feet." Vascular Surgery for Primary Care Providers, Seattle, WA. May 8, 1992.

Presentation: "Ischemic Gastropathy: A Lethal Variation of the Ischemic Mesenteric Syndrome." Annual Meeting, Washington State Chapter, American College of Surgeons. Chelan, WA. June 17, 1992.

Presentation: "Renal Vascular Surgery." Department of Surgery Forum, Virginia Mason Medical Center. Feb. 9, 1993.

Presentation: "Dialysis Access Grafts & Fistulae." Skagit County Surgeons, United General Hospital. April 26, 1993.

Presentation: "Carotid Artery Disease -- Surgical Perspectives." Cascade Valley Hospital. May 4, 1993.

Presentation: "Vascular Disease & Extremity Wounds." Wound Care Symposium, Virginia Mason Medical Center, Seattle, WA. May 24, 1993.

Presentation: "Vascular Surgery in Primary Care Practice." Sequim Physicians, Sequim Medical Plaza, Sequim, WA. Sept. 16, 1993.

Presentation: "Renal Artery Dissection." Annual Meeting, Washington State Chapter, American College of Surgeons, June 1994.

Presentation: "Renovascular Disease: Surgical Options." Seattle Surgical Society, Seattle, WA.

Sept. 26, 1994.

Presentation: "Primer on Carotid, Aortic, and Femoral Popliteal Disease." Annual Critical Care Conference, Port Angeles, WA. Oct. 29, 1994.

Presentation: "Non-atheromatous Carotid Artery Disease." Cerebrovascular Update 1995, Seattle, WA. April 28, 1995.

Presentation: "Patient Satisfaction and Outcome Following Carotid Endarterectomy Using a Selective Policy of Local Anesthesia." Annual Meeting, Seattle Surgical Society, Seattle, WA. Jan. 15, 1998 (Ryan)

Presentation: "Vascular Diagnosis in a Primary Care Practice." Olympic Memorial Hospital, Port Angeles, WA. March 18, 1998.

Presentation: "Venous Disorders: Facts, Myths, and Practical Information." Symposium: Surgical Issues for Primary Care Providers, Seattle, WA. March 27, 1998.

Presentation: "Vascular Diagnosis and Treatment." Jefferson General Hospital, Port Townsend, WA. Dec. 9, 1998.

Presentation: "Patient-Derived Outcomes Assessment: Implications in Managing Carotid Atherosclerosis." Grand Rounds, Virginia Mason Medical Center, Seattle, WA. Oct. 23, 1998.

Presentation: "Carotid Surgery Update." The Surgeons Travel Club, Seattle, WA. April 30, 1999.

Presentation: "Lower Extremity Vascular Disorders." Grand Rounds, Virginia Mason Medical Center, Seattle, WA April 2001.

Presentation: "Lower Extremity and Foot Ischemia." Annual Meeting, Washington State Podiatric Association, Skamania, WA. April 2001.

Presentation: “Leg Pain.” The Art of Referral to the Allopathic Provider. Northwest Hospital. Seattle, WA. Dec 2002.

Presentation: “Endovascular Repair of Abdominal Aortic Aneurysms.” Grand Rounds, Northwest Hospital, Seattle, WA. September, 2003

Presentation: “Endovascular AAA Repair.” Puget Sound Chapter, American Association of Critical Care Nurses, Annual Meeting. Seattle, WA. September, 2003

Presentation: “Lower Extremity Amputation.” Washington Chapter, American College of Surgeons, Annual Meeting, Chelan, WA, June 2004.

Presentation: “Wound Care: The Essentials.” Wound Care Symposium. Seattle, WA, Sept 2005

Presentation: “Surveillance Duplex Studies: What the Vascular Surgeon Wants to Know.” Annual Meeting, NW Vasc Technologists. Sea-Tac, WA, Nov. 2007

Washington State Health Care Authority

Negative-pressure Wound Therapy

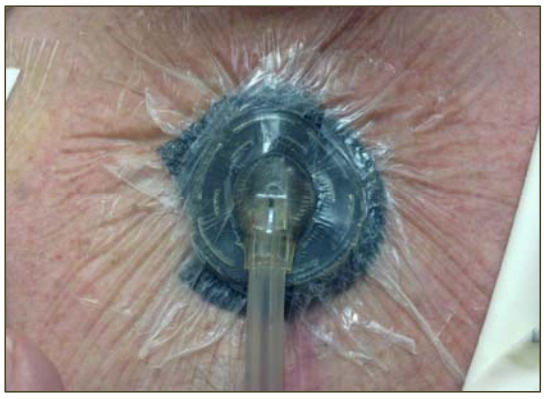
November 18, 2016

Shana Johnson, MD
Medical Officer CQCT/CLIN EVAL/MO
Washington Health Care Authority

Washington State Health Care Authority

Negative Pressure Wound Therapy

- The application of negative pressure (suction) to the surface of a wound
- Promotes healing by promoting ideal wound healing environment (moist, clean wound base)



NPWT 2

Negative Pressure Wound Therapy

What is the clinical effectiveness of NPWT in the **home or outpatient** settings for treatment of chronic wounds:

- Diabetic foot ulcers
- Venous ulcers
- Arterial ulcers
- Pressure ulcers
- Mixed etiology chronic wounds
- Surgical wounds

NPWT 3

Agency Medical Director Concerns

- **SAFETY = MEDIUM**
- **EFFICACY = MEDIUM/HIGH**
- **COST = MEDIUM**

NPWT 4

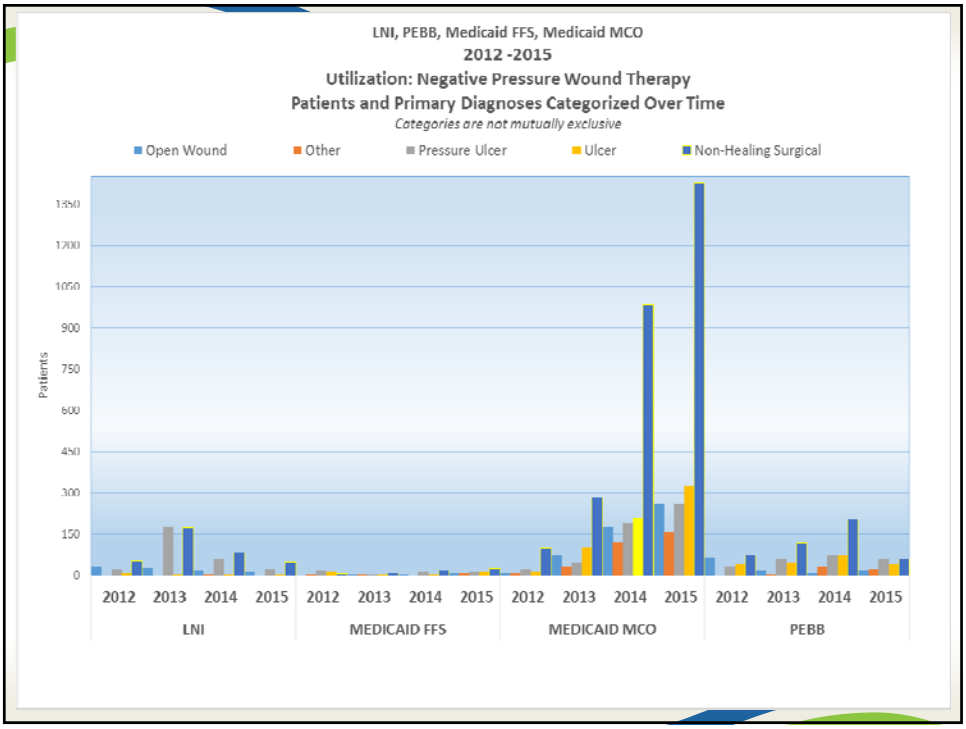
PEBB/UMP (No Medicare), Medicaid Managed (MCO) and Fee-For-Service, and LNI

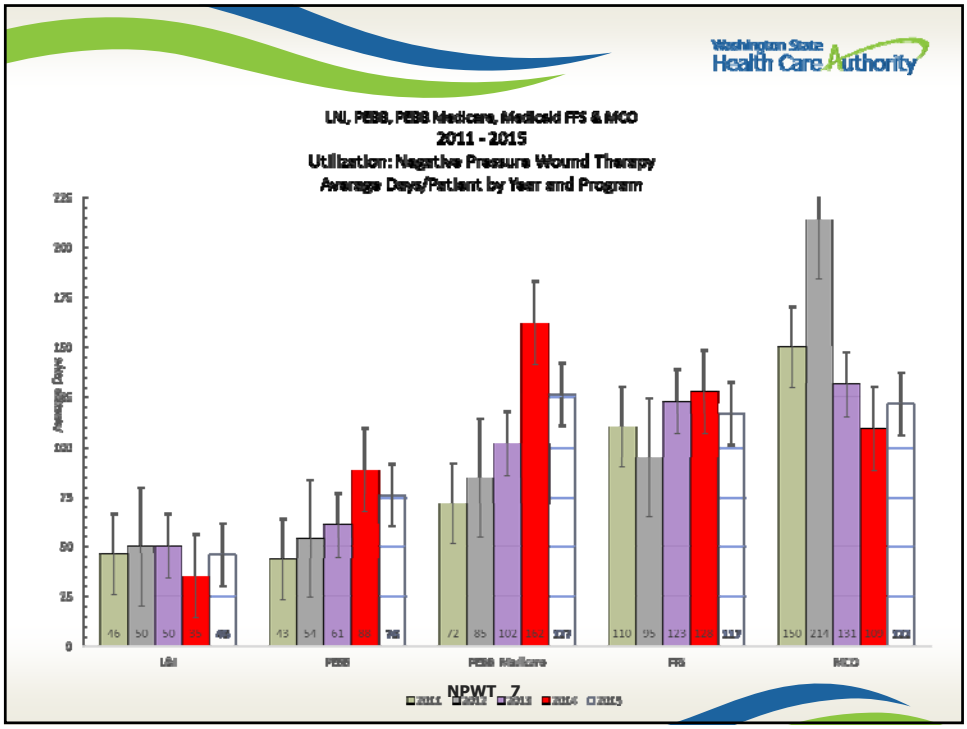
2011 – 2015 Negative Pressure Wound Therapy
All Diagnoses Site of Care

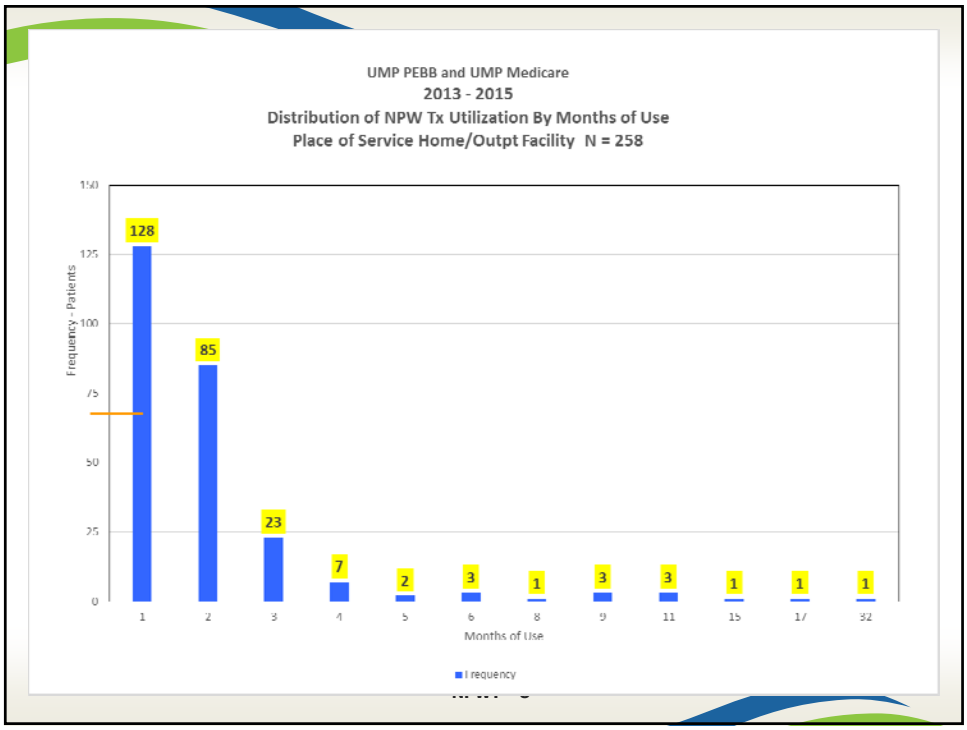
	Distribution		
Place of Service/Type of Facility	PEBB/UMP	Medicaid/FFS & MCO	LNI
Home/Office	92%	74%	100%
Inpt Hosp	7%	<1%	0%
Other*	1%	25%	0%

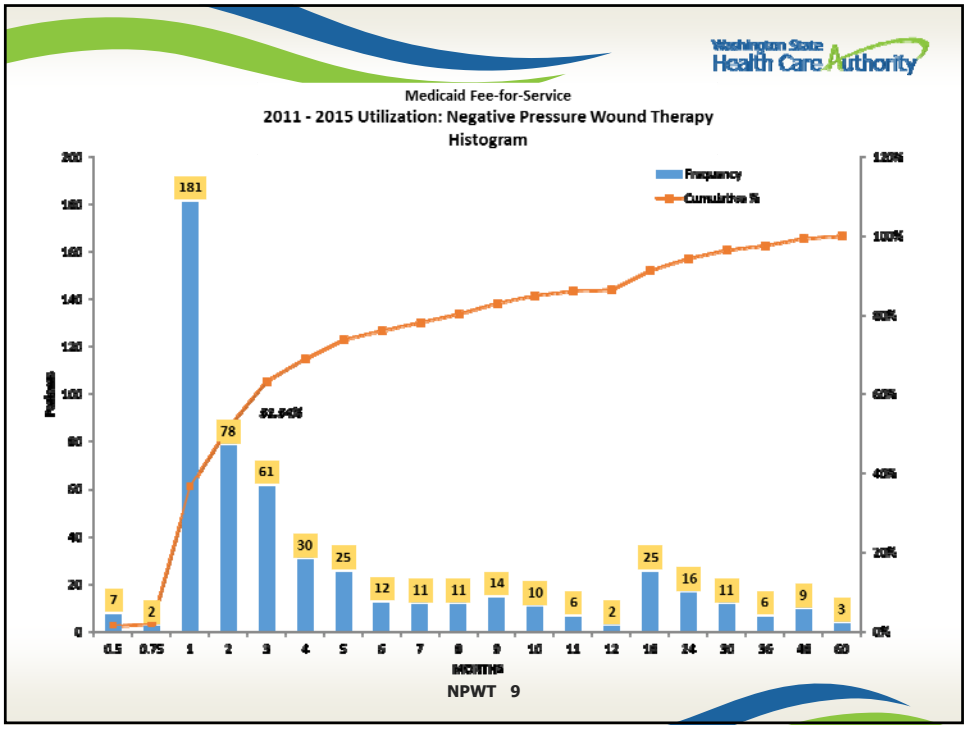
'* Skilled Nursing Facility, Ambulatory Surgery Center, Emergency Room

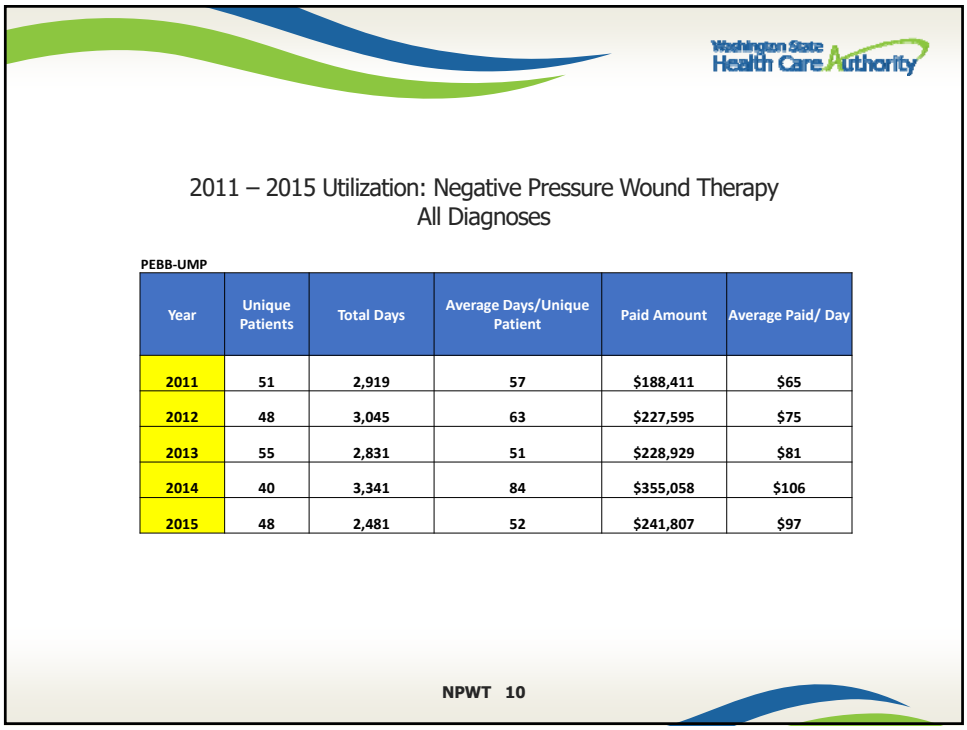
NPWT 5




Washington State Health Care Authority
LNI, PEBB, PEBB Medicare, Medicaid FFS & MCO
2011 - 2015
Utilization: Negative Pressure Wound Therapy
Average Days/Patient by Year and Program
Average Days
LNI
PEBB
PEBB Medicare
FFS
MCO
NPWT_7


UMP PEBB and UMP Medicare
2013 - 2015
Distribution of NPW Tx Utilization By Months of Use
Place of Service Home/Outpt Facility N = 258
Frequency - Patients
Months of Use
Frequency
128
85
23
7
2
3
1
3
3
1
1
1


Medicaid Fee-for-Service
2011 - 2015 Utilization: Negative Pressure Wound Therapy
Histogram
Frequency
Cumulative %
Patients
MONTHS
7
2
181
78
61
30
25
12
11
11
14
10
6
2
25
16
11
6
9
3
0.5
0.75
1
2
3
4
5
6
7
8
9
10
11
12
18
24
30
36
48
60
NPWT 9


2011 – 2015 Utilization: Negative Pressure Wound Therapy
All Diagnoses
PEBB-UMP
Year
Unique Patients
Total Days
Average Days/Unique Patient
Paid Amount
Average Paid/ Day
2011 51 2,919 57 $188,411 $65
2012 48 3,045 63 $227,595 $75
2013 55 2,831 51 $228,929 $81
2014 40 3,341 84 $355,058 $106
2015 48 2,481 52 $241,807 $97
NPWT 10

2011 – 2015 Utilization: Negative Pressure Wound Therapy - All Diagnoses

Medicaid Fee For Service

Year	Unique Patients	Total Days	Average Days/Unique Patient	Allowed Amount	Average Allowed/ Unique Patient
2011	205	22,540	110	$35,920	$175
2012	183	17,342	95	$31,048	$170
2013	158	19,362	123	$126,405	$800
2014	124	15,819	128	$34,204	$276
2015	141	16,478	117	$35,765	$254

Medicaid Managed Care

Year	Unique Patients	Total Days	Average Days/Unique Patient	Allowed Amt	Average Allowed/ Unique Patient
2011	54	7,647	142	$12,892	$239
2012	88	11,325	129	$30,624	$348
2013	158	18,011	114	$163,977	$1,038
2014	331	36,323	110	$270,734	$818
2015	541	66,724	123	$686,369	$1,269

NPWT 11

Current State Agency Policy

PEBB— Covered, no policy published

Medicaid FFS— Covered with conditions

Labor and Industries– Covered with conditions

Dept. of Corrections—Covered

NPWT 12

Labor & Industry Policy

Coverage Decision

NPWT is used in carefully selected patients whose wounds are not responsive to standard forms of treatment, or are at high risk of failing to heal as described below.

Indications for use:

- Stage III or IV pressure ulcer
- Diabetic/Neuropathic ulcer
- Venous or arterial insufficiency ulcer
- Chronic ulcers of mixed etiology present for at least 30 days
- Acute wounds induced by surgery or trauma
- Wounds that have received skin grafts, where there are medical factors that are likely to slow or prevent healing
- Poststernotomy mediastinitis, inpatient only

Continuation of coverage-- only if wound healing is evident

NPWT 13

Medicaid-FFS Policy

Coverage Criteria

Stage 3 or 4 pressure ulcer

Other wound care alternatives such as wet to dry have been tried and failed with wound present for at least 30 days.

Complications of a surgically created wound

Other wound care alternatives such have been tried and failed and it has been at least 6 weeks since surgery.

All other requests will be considered on a case-by-case basis based on medical necessity.

Continuation of coverage—considered on a case by case basis based on medical necessity

NPWT 14

Noridian

Coverage Criteria

A complete wound therapy program must have been tried or considered prior to NPWT

- chronic Stage III or IV pressure ulcer
- neuropathic (for example, diabetic) ulcer
- venous or arterial insufficiency ulcer
- chronic (being present for at least 30 days) ulcer of mixed etiology

Discontinuation of coverage:

- Any measurable degree of wound healing has failed to occur over the prior month. Wound healing is defined as improvement occurring in either surface area (length times width) or depth of the wound
- 4 months (including the time NPWT was applied in an inpatient setting prior to discharge to the home) have elapsed using an NPWT pump in the treatment of the most recent wound

NPWT 15

Aetna

Coverage Criteria

Aetna considers negative pressure wound therapy (NPWT) pumps medically necessary in Home setting if a complete wound therapy program (moist wound environment, debridement, nutrition status optimization) has been tried or considered prior to NPWT.

- chronic Stage III or IV pressure ulcer
- neuropathic ulcer (e.g., diabetic ulcer)
- venous or arterial insufficiency ulcer
- chronic ulcer of mixed etiology

Discontinuation Criteria

- Any measurable degree of wound healing has failed to occur over the prior month.
- Four months (including the time NPWT was applied in an inpatient setting prior to discharge to the home) have elapsed using an NPWT pump in the treatment of any wound. The medical necessity of NPWT beyond 4 months will be given individual consideration based upon required additional documentation

NPWT 16

Technology Report Summary

Diabetic foot ulcers: Favor NPWT, Blume 2008, RCT, Quality fair--greater proportion achieved closure and fewer secondary amputations in NPWT group

Arterial & venous ulcers: Favor NPWT, Yao 2012, Retro chart review, Quality very low

Pressure ulcers: Non-significant, Ford 2007, small RCT, Yao 2012, Quality very low

Mixed ulcer population: Favors NPWT, Lerman 2010, prospective cohort, Quality very low

Surgical wounds: Heterogeneous study population, no diff or favors NPWT

NPWT 17

Summary

There is some indication that NPWT may improve wound healing

The use of NPWT is commonly used in the treatment of certain types of wounds

The body of evidence available is insufficient (few good quality RCTs) to clearly prove an additional clinical benefit of NPWT

NPWT 18

Agency Recommendations

Cover with conditions following appropriate step therapy

General wound care measures

For all ulcers and wounds, the following components of a wound therapy program have been tried prior to application of NPWT:

- Application of dressings to maintain a moist wound environment, *and*
- Debridement of necrotic tissue if present, *and*
- Documentation of evaluation, care, and wound measurements by a licensed medical professional, *and*
- Evaluation of and provision for adequate nutritional status.

NPWT 19

Diabetic/Neuropathic ulcer

- *Comprehensive diabetic management program, and*
- *Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities.*

Venous ulcers

- *Compression bandages and/or garments have been consistently applied, and*
- *Leg elevation and ambulation have been encouraged.*

Pressure ulcers

- *Client has been appropriately turned and positioned, and*
- *Client has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis and*
- *Moisture and incontinence have been appropriately managed.*

Arterial ulcers

Chronic ulcers of mixed etiology

Surgical wounds

NPWT 20

Discontinuation Criteria

- Any measurable degree of wound healing has failed to occur over the prior month. Wound healing is defined as improvement occurring in either surface area (length times width) or depth of the wound.
- Four months (including the time NPWT was applied in an inpatient setting prior to discharge to the home) have elapsed using an NPWT pump in the treatment of any wound. The medical necessity of NPWT beyond 4 months will be given individual consideration.

Contraindications to NPWT

- The presence in the wound of necrotic tissue with eschar, if debridement is not attempted; or
- Osteomyelitis within the vicinity of the wound that is not concurrently being treated with intent to cure; or
- Cancer present in the wound; or
- The presence of an open fistula to an organ or body cavity within the vicinity of the wound.

NPWT 21

Questions?

More Information:

http://www.hca.wa.gov/about-hca/health-technology-assessment/negative-pressure-wound-therapy

22

Washington State Health Care Authority

Order of scheduled presentations:

Negative pressure wound therapy – Home use

	Name
1	William E. Struyk, Advanced Medical Technology Association
2	Sharon Whalen, Acelity
3	Carmen Hudson, MD, FACS, CWSP, Swedish Medical Center
4	Randall Carson, Smith & Nephew
5	

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.		X *
2.	Equity interests such as stocks, stock options or other ownership interests.		X
3.	Status or position as an officer, board member, trustee, owner.		X
4.	Loan or intellectual property rights.		X
5.	Research funding.		X
6.	Any other relationship, including travel arrangements.		X

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

* MY SHARE OF RETAINER FS $7500

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).	X	

If yes to #7, provide name and funding Sources: ADVANCED MEDICAL TECHNOLOGY ASSN AKA ADVAMED. MEMBER ASSESSMENTS

*If you believe that you do not have a conflict, but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.*

I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

X [redacted] 10/20/16 WILLIAM E. STRUYK

Signature *Date* *Print Name*

So we may contact you regarding your presentation, please provide the following:

Email Address: WSTRUYK@GMAIL.COM

Phone Number: 360-600-2242

Health Technology Assessment Program
Negative Pressure Wound Therapy
November 18, 2016

William Struyk
Advanced Medical Technology Association

Negative Pressure Wound Therapy

- Goals
  - Make health care safer by relying on scientific evidence and a committee of practicing clinicians.
  - Ensure consistent coverage decisions for state agencies.
  - **Help make state-purchased health care more cost effective by paying for medical tools and procedures that are proven to work.**
  - Ensure the coverage decision process is open and inclusive by holding public meetings, sharing information, and publishing decision criteria and outcomes.

Source: HTAP Web page http://www.hca.wa.gov/about-hca/health-technology-assessment

Negative Pressure Wound Therapy

- Evidence Not Given Sufficient Weight in Current Process:
  - Coverage Policies of Health Plans

From Blue Cross Blue Shield Association is an association of independent Blue Cross and Blue Shield companies. © 2016 Blue Cross Blue Shield Association. Original Review Date: Jul 1998 Current Review: Jan 2016 Next Review: Jan 2017

Indication 2: Individuals with chronic wounds and co-morbidities affecting wound healing who are treated with negative pressure wound therapy.	Evidence Level Moderate for 2014 2015 2016 2017
The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome. (Emphasis added)	

  - Plans Covering NPWT Subject to Criteria Group Health, Regence*, Noridian, Oregon Health Evidence Review Commission*

Not accurately reported in the Hayes Draft Report

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.	✓	
2.	Equity interests such as stocks, stock options or other ownership interests.		✓
3.	Status or position as an officer, board member, trustee, owner. Employee	✓	
4.	Loan or intellectual property rights.		✓
5.	Research funding.		✓
6.	Any other relationship, including travel arrangements.	✓	

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

Employee of ACelity

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		

If yes to #7, provide name and funding Sources: _____

*If you believe that you do not have a conflict, but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.*

I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

X [redacted]
Signature *Date*

Sharon Whalen
Print Name

So we may contact you regarding your presentation, please provide the following:

Email Address: Sharon.Whalen@acelity.com

Phone Number: (949) 241-6205

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.		x
2.	Equity interests such as stocks, stock options or other ownership interests.		x
3.	Status or position as an officer, board member, trustee, owner.		x
4.	Loan or intellectual property rights.		X
5.	Research funding.		X
6.	Any other relationship, including travel arrangements.		x

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		X

If yes to #7, provide name and funding Sources: Work for Swedish Medical Group; residential care team and Cherry Hill Outpatient Wound Healing Center.

*If you believe that you do not have a conflict, but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.*

I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

X [redacted] 10/28/16 Carmen Hudson

Signature *Date* *Print Name*

So we may contact you regarding your presentation, please provide the following:

Email Address: carmen.hudson@swedish.org

Phone Number: 206-310-9576

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.	X	
2.	Equity interests such as stocks, stock options or other ownership interests.		X
3.	Status or position as an officer, board member, trustee, owner.		X
4.	Loan or intellectual property rights.		X
5.	Research funding.		X
6.	Any other relationship, including travel arrangements.		X

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

Smith & Nephew, Inc., Director, Government Affairs & Reimbursement, N.A.

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		X

If yes to #7, provide name and funding Sources:

*If you believe that you do not have a conflict, but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.*

I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

X [redacted] **10-28-2016** **Randall R. Carson**

Signature *Date* *Print Name*

So we may contact you regarding your presentation, please provide the following:

Email Address: randall.carson@smith-nephew.com

Phone Number: 401-241-9043

Clinical Evidence

smith&nephew

PICO®

Single Use
Negative Pressure
Wound Therapy System

PICO◇ Clinical Evidence

Obstetrics and Gynaecology

Authors	Title	Journal and availability	Type
Bullough *et al*	**Reducing C-Section wound complications**	The Clinical Services Journal (April 2015) Open access: http://www.smith-nephew.com/global/assets/uki/bullough%202015%20print%20version.pdf Reference: PCCE-97-1115-UE	• Prospective Case Cohort + Retrospective Audit
Bullough *et al*	**Changing wound care protocols to reduce post-operative caesarean section complications**	Open access. Can be downloaded from: http://www.wounds-uk.com/pdf/content_11287.pdf Reference: PCCE-83-0615-USE	• Prospective Case Cohort
Hickson et al	**A journey to zero: reduction of post-operative caesarean Surgical Site Infections over a five-year period**	Surg Infections (2015) 16(2): 174-177 Open access: http://online.liebertpub.com/loi/SUR Reference: IMCE-07-0415-USE	• Retrospective audit
Harris J, et al	**Using a multi-faceted active change process and infection prevention to reduce post-op C-section infection**	Poster presented at SAWC Spring 2013 http://www.ajicjournal.org/article/S0196-6553(12)00318-5/abstract Reference: PVCE-03-0313-NAE	• Clinical protocol including PICO
Ream et al	**What happens when you cross an ET with an OB nurse? Preventing wound dehiscence and surgical site infections using single use negative pressure therapy system in post-op C-section patients with BMI ≥ 35**	Poster presented at the 2014 CAWC conference Reference: PCCE-46-1014-NAE	• Case series
Fumarola et al	**The management of a dehisced surgical wound in a pregnant lady using a new portable negative pressure wound therapy (NPWT) device**	This poster was presented in Wounds UK, Harrogate, 2013 www.wounds-uk.com Reference: PCCE-56-0914-NAE	• Case study

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Orthopedic Surgery

Authors	Title	Journal and availability	Type
Adogwa *et al*	**Negative Pressure Wound Therapy reduces incidence of post-op wound infections and dehiscence after long-segment Thoracolumbar Spinal Fusion: A single institutional experience**	The Spine J (2014) doi:10.1016/j.spinee.2014.04.011 Subscription, ScienceDirect or direct purchase: http://www.sciencedirect.com/science/article/pii/S1529943014003982# Reference: PCCE-75-0315-USE	• Retrospective audit of case and control cohorts
Gillespie *et al*	**End-users' assessment of prophylactic Negative Pressure Wound Therapy products**	Wound Prac Res (2013) 21(2): 74-81 Subscription or direct purchase: http://search.informit.com.au/documentSummary;dn=394481190522228;res=IELHEA Reference: PCCE-85-0615-USE	• Case series
Karlakki *et al*	**Negative Pressure Wound Therapy for management of the surgical incision in orthopaedic surgery**	Bone Joint Res (2013) 2: 276-84 Open access: http://www.bjr.boneandjoint.org.uk/content/2/12/276.full Reference: PCCE-44-0414-NAE	• Literature review of 33 Publications identified for closed incisions
Matsumoto and Parekh	**Use of Negative Pressure Wound Therapy on closed surgical incision after total ankle arthroplasty**	Foot and Ankle International (2015) doi: 10.1177/1071100715574934 Subscription, Open access or direct purchase http://fai.sagepub.com/content/early/2015/03/03/1071100715574934.full.pdf+html Reference: PCCE-89-0715-UE	• Retrospective comparative study
Nordmeyer *et al*	**Negative Pressure Wound Therapy for seroma prevention and surgical incision treatment in spinal fracture care**	Int Wound J (2015) Doi: 10.1111/iwj.12436 Open access: http://onlinelibrary.wiley.com/doi/10.1111/iwj.12436/abstract Reference: PCCE-90-0715-USE	• Randomized control trial
Hudson et al.,	**Simplified NPWT: clinical evaluation of an ultraportable, no-canister system**	**Int Wound J** (2013) doi:10.111/iwj.12080 Open access: http://onlinelibrary.wiley.com/doi/10.1111/iwj.12080/pdf Reference: PCCE-38-0513-NAE	• Case series
Sharp	**An evaluation of PICO negative pressure dressings for complex orthopedic surgical wounds.**	This poster was presented at Wounds UK, Harrogate November 2012 Reference: PCCE-32-1112-NAE	• Case series

PICO◇ Clinical Evidence

Orthopedic Surgery

Authors	Title	Journal and availability	Type
Ember *et al*	**An evaluation of a portable single use negative pressure wound therapy (NPWT) dressing to reduce wound complications in pediatric spinal surgery**	This poster was presented at Wounds UK, Harrogate November 2013 Open access: http://www.wounds-uk.com/pdf/cases_11013_224.pdf Reference: PCCE-57-0914-NAE	• Case series 40 patients
Luciani et al	**Usage of Disposable Negative Pressure Device for Tissue Reparation in Orthopedics.**	This poster was presented at X Congresso Nationale AIUC, Ancona. September 2011 Reference: PCCE-15-0212-NAE	• Case series
Daniel et al	**The treatment of an intra-articular calcaneus fracture in an individual with multiple comorbidities with a new single use negative pressure wound therapy (NPWT) system without an exudate canister.**	Poster presented at SAWC 2012 Reference: PCCE-26-1012-NAE	• Case study

Plastic Surgery

Authors	Title	Journal and availability	Type
Galiano et al	**A prospective, randomized, intra-patient, comparative, open, multi-center study to evaluate the efficacy of a single use negative pressure wound therapy (NPWT) system* on the prevention of post-surgical incision healing complications in patients undergoing bilateral breast reduction surgery**	This poster was presented at The British Association of Aesthetic Plastic Surgeons (BAAP's) 30th Annual Scientific Meeting, London, September 2014 Reference: PCCE-61-0914-NAE	• Prospective Study. 200 patients undergoing bilateral reduction mammoplasty,
Twyman et al	**The significance of PICO Single Use Negative Pressure Wound Therapy (NPWT) on wellbeing for plastic surgery outpatients**	This poster was presented in Wounds UK, Harrogate, 2013 Open access: http://www.wounds-uk.com/pdf/cases_11013_268.pdf Reference: PCCE-58-0914-NAE	• Case series
Edwards et al	**Use of a portable negative pressure wound therapy system (NPWT) (PICO) for split thickness skin grafts.**	This poster was presented at Wounds UK, Harrogate November 2012 Reference: PCCE-33-1112-NAE	• Case series

PICO◇ Clinical Evidence

Colorectal Surgery

Authors	Title	Journal and availability	Type
Pellino *et al*	**Effects of a new pocket device for Negative Pressure Wound Therapy on surgical wounds of patients affected with Crohn's Disease: A pilot trial**	Surg Innov (2013) doi: 10.1177/1553350613496906 Subscription or direct purchase http://sri.sagepub.com/content/21/2/204.long Reference: PCCE-72-0215-USE	• Controlled trial 30 patients.
Selvaggi *et al*	**New advances in Negative Pressure Wound Therapy (NPWT) for surgical wounds of patients affected with Crohn's Disease**	Available with subscription, ScienceDirect, or direct purchase http://www.journal-surgery.net/article/S1743-9191(14)00862-0/pdf Reference: PCCE-65-1114-USE	• Prospective case control study
Rylands et al	**The use of PICO Single Use Negative Pressure Wound Therapy (NPWT) System in the management in the management of a complex dehisced abdominal wound.**	This poster was presented at Wounds UK, Harrogate November 2011 Reference: PCCE-06-0412-NAE	• Case study

Cardiothoracic Surgery

Authors	Title	Journal and availability	Type
Witt-Majchrak *et al*	**Preliminary outcome of treatment of postoperative primary closed sternotomy wounds treated using Negative Pressure Wound Therapy**	Polski Przeglad Chirurgiczny (2014) Vol 86 (10): 456-65 Open access: http://www.degruyter.com/view/j/pjs.2014.86.issue-10/pjs-2014-0082/pjs-2014-0082.xml Reference: PCCE-91-0715-USE	• Randomized control trial 80 patients

Mode of Action

Authors	Title	Journal and availability	Type
Malmsjo *et al.,*	**Biological effects of a disposable, canister-less NPWT system.**	**ePlasty** (2014) 14:1-15 Open access: http://www.owm.com/supplements?page=1 Reference: PCCE-48-0514-NAE	• Preclinical study
Malmsjo et al	**Pre-clinical assessment of a simplified NPWT device (PICO)**	Poster presented at SAWC, Las Vegas 2011 Reference: PCCE-04-0911-NAE	• Preclinical study

PICO◇ Clinical Evidence

Multi-discipline

Authors	Title	Journal and availability	Type
Campitiello *et al*	**Portable Topical Negative Pressure: its hypothetical application in the prevention of surgical site infect. Pilot Study**	This Poster was presented at X Congresso Nazionale AIUC Ancona 21-24 Settembre 2011 Reference: PCCE-14-0212-NAE	• Case Study
Hudson *et al*	**Simplified Negative Pressure Wound Therapy: clinical evaluation of ultraportable, no canister system**	Int Wound J (2013) doi:10.111/iwj.12080 Open access: http://onlinelibrary.wiley.com/doi/10.1111/iwj.12080/pdf Reference: PCCE-38-0513-NAE	• Safety and efficacy study
Hurd *et al*	**Use of a Portable, Single Use Negative Pressure Wound Therapy Device in Home Care Patients with Low to Moderately Exuding Wounds: A case Series**	Ostomy Wound Management (2014) 60(3): 30:36. (326 patients series) Downloaded, with free registration to OWM http://www.o-wm.com/article/use-portable-single-use-negative-pressure-wound-therapy-device-home-care-patients-low-modera Reference: PCCE-43-0414-NAE	• Case series 326 patients with PICO compared to retrospective data of patients under tNPWT
Leak	**A case-series appraisal of Single Use Negative Pressure Wound Therapy system in secondary care**	This poster was presented at Wounds UK, Harrogate November 2011 Open access: http://www.wounds-uk.com/pdf/cases_10239_130.pdf Reference: PCCE-11-0412-NAE	• Case Series
Hudson et al	**Clinical assessment of a simplified single use NPWT device (PICO).**	Poster presented at SAWC, Las Vegas 2011 Reference: PCCE-03-0911-NAE	• Case series 20 patients
Russell et al	**Clinical experience of a new negative pressure dressing in two acute patients.**	Poster presented at Wounds UK, Harrogate, 2011 Reference: PCCE-13-0412-NAE	• Case study
Wuamett et al	**Single use negative pressure wound therapy (SU-NPWT) for the management of vascular surgery incisions**	Poster presented at EWMA 2013 Reference: PCCE-59-0914-NAE	• Case series 12 patients

PICO◇ Clinical Evidence

Wound Care

Authors	Title	Journal and availability	Type
Dowsett *et al*	**Venous leg ulcer management: Single Use Negative Pressure Wound Therapy**	Journal of Wound Care (March 2014) S16-S25. Copyright purchased for unlimited distribution. PDF available. Reference: PCCE-84-0615-USE	• Output of a nurse advisory panel
Hurd *et al*	**Evaluating the costs and benefits of innovation in chronic wound care products and practices**	Ostomy Wound Management supplement to June 2013 issue . Open access: http://www.o-wm.com/files/owm/SN-supp-june.pdf Reference: PCCE-86-0615-USE	• Case series
Murphy et al	**Pilonidal sinus wounds : Successful use of the novel negative pressure wound therapy device PICO**	Poster presented at Wounds UK. 2013; 9: 80–83 Reference: PCCE-87-0615-USE	• Case study
Deroo et al	**Outcomes of a Portable Single Use Negative Pressure Wound Therapy Trial.**	Poster presented at WUWHS Yokohama. 2012 Reference: PCCE-16-0512-NAE	• case series 198 patients
Atkinson	**The use of a new single use portable negative pressure dressing for the treatment of a vascular patient with a dehisced lower leg wound**	This poster was presented at Wounds UK, Harrogate November 2011 Reference: PCCE-09-0412-NAE	• Case study
Leak et al	**"The human and economic impacts of single use negative pressure wound therapy in a case of limb salvage. "**	This poster was presented at Wounds UK, Harrogate November 2012 Reference: PCCE-30-1112-NAE	• Case study
Leak et al	**The value of intervention: post-operative application of single use negative pressure wound therapy.**	This poster was presented at Wounds UK, Harrogate November 2012 Reference: PCCE-31-1112-NAE	• Case study
Brambilla et al	**Portable Topical Negative Pressure. Evaluation in Venous Ulcers and Skin Grafts.**	This Poster was presented at X Congresso Nazionale AIUC Ancona 21-24 Settembre 2011 Reference: PCCE-18-0512-NAE	• Case series
Davis et al	**A community-based case series appraisal of a single use negative pressure wound therapy (NPWT) system.**	This poster was presented at Wounds UK, Harrogate November 2011 Reference: PCCE-10-0412-NAE	• Case series

PICO◇ Clinical Evidence

Wound Care

Authors	Title	Journal and availability	Type
Dowsett et al	**Development of a clinical guideline for the implementation of a Single Use Negative Pressure**	This poster was presented at Wounds UK, Harrogate November 2012 Reference: PCCE-35-1112-NAE	• Case series
Ewald-Lind	**Clinical Experience of a New Single Use Negative Pressure Wound Therapy (NPWT) System in Hard to Heal Wounds**	Poster presented at SAWC 2012 Reference: PCCE-22-0612-NAE	• Case series
Fumarola et al	**Quality and Innovation: improving patient experience and clinical outcomes with new technology**	This poster was presented at Wounds UK, Harrogate November 2011 Reference: PCCE-07-0412-NAE	• Case study
Haycocks et al	**Single use negative pressure therapy following surgical debridement of a diabetic foot ulcer.**	This poster was presented at Wounds UK, Harrogate November 2011 Reference: PCCE-08-0412-NAE	• Case study
Nair et al	**Use of single use negative pressure wound therapy in refractory ulcers**	Poster presented at CSAWC Conference 2014 Reference: PCCE-08-0412-NAE	• Case series
Romanelli et al	**Venous Leg Ulcer, Compression Therapy and Negative Pressure: how to conciliate the necessary deambulation?**	Poster presented at Congresso Nazional AIUC, Ancona, 2011 Reference: PCCE-20-0512-NAE	• Case series
Wong et al	**Single use negative pressure wound therapy (suNPWT) system for wound healing in an outpatient clinic**	Poster presented at the 2014 CAWC Conference Reference: PCCE-63-1014-NAE	• Case series

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WA STATE: Washington Payers Coverage of Traditional and Single Use Negative Pressure Wound Therapy

PAYER	U.S.Commercial Covered Lives	U.S. Medicare Advantage Lives	State of Washington Covered Lives	Traditional NPWT Coverage (97605-97606)	Single Use NPWT Coverage (97607-97608)	COMMENTS
AETNA	19,956,642	1,251,498	341,262	Yes	No	Payer holds Single Use I&E
American Postal Workers	118,117	0	2,215	Yes	Yes	Benefits/Coverage through Union Collective Bargaining. Follows Medicare Guidelines and Coverage Directives.
AmeriHealth	12,546,329	19,108	6	Yes	No	Non-Coverage policy for Single Use NPWT. Holds Single Use NPWT I&E. Next Medical Policy Review 1/2017
Anthem / Wellpoint	33,986,000	483,373	141,319	Yes	No	Anthem (14 states) holds Single Use NPWT I&E
BridgeSpan Health	14,388	0	7,705	Unknown	Unknown	Unable to determine coverage. Secured Login by participating providers required.
Centene	489,300	415	209,400	Yes	Yes	Prior Authorization Required for Coverage
CIGNA	14,027,343	416,672	224,055	Yes	No	Payer holds Single Use I&E
Colville Federated Tribe	1,000	0	1,000	Yes	Yes	Part of NHS systems (few lives.) Follows Medicare LCD/Fee Schedules. No prior authorization. Supported Medical Necessity required.
Community Health Plan of Washington	307,707	4,302	306,707	Yes	Yes	Coverage confirmed via prior PICO Claim submissions
Federated Mutual	99,698	0	433	Yes	Yes	This is a primarily property/casuality company out of MN. Case management prevails and coverage will follow Medicare Guidelines. Prior Authorization and support by Case Managers required.
Geisinger	32,000	0	9	Yes	Yes	Positive coverage when criteria/and evidence of medical necessity provided.
GHI-Emblem	1,057,154	4,446	280	Yes	Yes	GHI/HIP Emblem Acquired by Group Health Inc. Positive coverage for GHI-Emblem and HIP-Emblem
Group Health Cooperative: *Will be acquired by Kaiser in 2016*	575,980	89,256	574,180	Yes	No	Will be acquired by Kaiser in 2016. Non-Coverage holds single use NPWT I&E and cites insufficient clinical evidence to advance coverage at this time. Next review opportunity will be 4/2017.
Health Alliance	170,110	23,594	5,127	Unknown	Unknown	Unable to determine coverage. Secured Login by participating providers required.
Health Net	1,120,000	238,400	8,000	Yes	Yes	Positive coverage when criteria/and evidence of medical necessity provided through prior authorization.
HIP Emblem	327,320	103,287	58	Yes	Yes	GHI/HIP Emblem Acquired by Group Health Inc. Positive coverage for GHI-Emblem and HIP-Emblem
Humana	2,236,000	3,237,500	35,400	Yes	No	Payer holds Single Use I&E

PAYER	U.S.Commercial Covered Lives	U.S. Medicare Advantage Lives	State of Washington Covered Lives	Traditional NPWT Coverage (97605-97606)	Single Use NPWT Coverage (97607-97608)	COMMENTS
Independence Blue Cross	743,013	99,932	10,321	Yes	No	Payer holds Single Use I&E. Next review for coverage 6/2017
Independent Health Association	148,247	93,697	2	Unknown	Unknown	Unable to determine coverage. Secured Login by participating providers required.
KAISER	6,155,849	972,346	82,064	Yes	Yes	Positive coverage and appropriate Traditional and Single Use NPWT CPT codes loaded into all Kaiser Claim Systems.
LifeWise	46,234	0	46,234	Yes	Yes	Coverage confirmed via prior PICO Claim submissions/Prior Authorization required.
MODA Health Care	348,723	13,420	47,648	Yes	Yes	Positive Coverage for Traditional and Single Use NPWT.
Molina Health Care	4,220,000	400	672,000	Yes	Currently in revie	Positive coverage for Traditional NPWT, Single Use currently in Medical Policy Update review.
Premera Blue Cross	2,100,000	25,334	2,010,289	Yes	Yes	Coverage Confirmed. Prior Authorization required.
Providence Health System	259,308	49,828	28,581	Yes	No	Single Use NPWT did not get approved by Providence Technology Assessment.
Regence Blue Cross - Blue Shield	482,535	56,813	22,122	Yes	Yes	Positive Coverage with Prior Authorization required under the terms of all Regence Benefit Plans. Supporting documentation may be requested.
Regence Blue Shield	701,369	23,779	701,369	Yes	Yes	Positive Coverage with Prior Authorization required under the terms of all Regence Benefit Plans. Supporting documentation may be requested.
Regence WA,OR, ID	133,492	6971	858	Yes	Yes	Positive Coverage with Prior Authorization required under the terms of all Regence Benefit Plans. Supporting documentation may be requested.
Sentara Health	145,394	0	26	Yes	Yes	A Not for Profit Health Organization primarily VA and few lives in WA. Guidelines support positive coverage.
SIHO Holding Insurance	32,571	0	2	Unknown	Unknown	Unable to determine coverage. Secured Login by participating providers required.
State of Washington	387,120	0	387,120	Yes	Unknown	Currently reviewing Single Use NPWT. History prevails and State of WA plans generally follow WA Cooperative. Their review will be done in 4/2017.
Timber Products Trust Plan	13,312	0	6260	Unknown	Unknown	Unable to determine coverage. Secured Login by participating providers required.
Trustmark Mutual	20,972	0	18,063			Researching for NPWT Medical Policy: May need to contact the payer by phone.
UHC	47,530,928	3,390,928	348,739	Yes	Yes	Positive coverage and appropriate Traditional and Single Use NPWT CPT codes loaded into all UHC/OPTUM Claim Systems.

PAYER	U.S.Commercial Covered Lives	U.S. Medicare Advantage Lives	State of Washington Covered Lives	Traditional NPWT Coverage (97605-97606)	Single Use NPWT Coverage (97607-97608)	COMMENTS
US Health Group	281,216	0	22	Unknown	Unknown	Primarily an Individual Insurance Group. Members encouraged to contact US Health for Prior Authorization of Services.

Negative Pressure Wound Therapy – Home Use

Hayes, Inc.
November 18, 2016

Shorthand and abbreviations

- **AE** – adverse event
- **AMWT** – advanced moist wound therapy
- **ATP** – active treatment phase
- **DFU** – diabetic foot ulcer
- **FQ** – fair quality
- **GL** – guideline
- **HR** – hazard ratio
- **IQR** – interquartile range
- **KQ** – key question
- **MRI** – magnetic resonance imaging
- **NPWT** – negative pressure wound therapy
- **n** – number of patients
- **NR** – not reported
- **NS** – not significant
- **Obs** – observational
- **PICOS** – population, intervention, comparator, outcomes, setting
- **PQ** – poor quality
- **PU** – pressure ulcer
- **QALY** – quality-adjusted life-year
- **QOL** – quality of life
- **RCT** – randomized controlled trial
- **SNaP** – Smart Negative Pressure Wound Care System
- **Std tx** – standard treatment
- **VAC** – vacuum-assisted closure negative pressure wound therapy (generic term)
- **V.A.C.** – Vacuum-Assisted Closure Negative Pressure Wound Therapy System (brand name)
- **VAS** – visual analog scale
- **VLU** – venous leg ulcer

2

Presentation overview

- Background
- Scope, Methods, and Search Results
- Findings
- Practice Guidelines and Payer Policies
- Overall Summary and Discussion

Background

Negative Pressure Wound Therapy

- Involves the application of subatmospheric pressure (suction) to the surface of a wound
- Provides a warm, moist wound bed and removes wound fluid
- Devices may:
  - remove molecular factors that inhibit cell growth
  - promote cell proliferation
  - improve blood flow to the wound
  - promote angiogenesis
  - enhance wound oxygenation
  - improve the flow of nutrients to the wound
  - create mechanical forces that draw the wound edges together

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Negative Pressure Wound Therapy

- NPWT consists of the application of a foam or gauze-type dressing sealed with an adhesive film and connected via tubing to a vacuum pump
- Continuous or intermittent controlled negative pressure (suction) is applied across the wound
- Wound effluent is collected in a canister

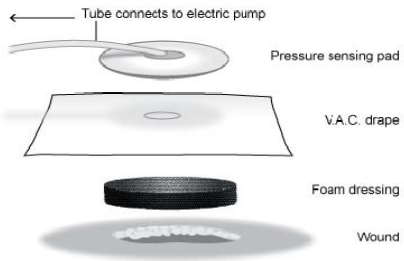

Figure 1. Negative Pressure Wound Therapy System

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Negative Pressure Wound Therapy

Characteristics of NPWT Systems:

- Numerous NPWT devices are commercially available.
- Devices vary in many aspects, including:
  - size
  - portability
  - source of power (e.g., electric, battery, or constant force spring)
  - ability to add instillation fluid
  - ability to vary the negative pressure settings
  - types of wound dressings
- Some NPWT systems include a continuous use pump and disposable canister; others include disposable pumps and canisters.
- Dressing changes are typically performed every 48 to 72 hours and no less than 3 times per week for most models; some models are designed to stay in place for 7 days.

Negative Pressure Wound Therapy

Potential Benefits of NPWT:

- Symptom management
- Reduced frequency of dressing changes
- Cost-effectiveness compared with alternative therapies because of faster healing times that may lead to lower overall treatment costs

Potential Harms Associated with NPWT:

- Pain
- Retention of dressing material
- Bleeding
- Infection
- Death from infection or bleeding
- Complications from loss of electricity

Negative Pressure Wound Therapy

FDA Public Health Notification and Advice for Patients (2009):

- Alert regarding the risk of death and serious complications, especially bleeding and infection
- Recommendations to reduce the risk
- Complications are rare but can occur wherever NPWT systems are used
- Most of the reports of deaths (n=6) and serious injuries (n=77) between 2007 and 2009 occurred at home or in a long-term care facility

Updated FDA Notice (2011):

- Reports of 6 more deaths and 97 more injuries (total between 2007 and 2011 of 12 deaths and 174 injuries)
- 3 of the additional death reports indicated that the patients were receiving NPWT at home or in a nursing home
- In more than half of the additional injury reports identifying the location of care, adverse events occurred either at home or in a long-term care facility
- Infection was the most commonly reported injury, and bleeding continued to be the most serious adverse event

Negative Pressure Wound Therapy

Contraindications

- Necrotic tissue with eschar present
- Untreated osteomyelitis
- Non-enteric and unexplored fistulas
- Malignancy in the wound
- Exposed vasculature
- Exposed nerves
- Exposed anastomotic site
- Exposed organs

Food and Drug Administration (FDA). UPDATE on Serious Complications Associated with Negative Pressure Wound Therapy Systems: FDA Safety Communication. February 24, 2011. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm244211.htm. [Archived Content]

Negative Pressure Wound Therapy

Patient Risk Factors

- Patients at high risk for bleeding and hemorrhage
- Patients on anticoagulants or platelet aggregation inhibitors
- Patients with:
  - friable vessels and infected blood vessels
  - vascular anastomosis
  - infected wounds
  - osteomyelitis
  - exposed organs, vessels, nerves, tendons, and ligaments
  - sharp edges in the wound (i.e., bone fragments)
  - spinal cord injury (stimulation of sympathetic nervous system)
  - enteric fistulas
- Patients requiring:
  - MRI
  - Hyperbaric chamber
  - Defibrillation
- Patient size and weight
- Use near vagus nerve (bradycardia)
- Circumferential dressing application
- Mode of therapy – intermittent versus continuous negative pressure

Food and Drug Administration (FDA). UPDATE on Serious Complications Associated with Negative Pressure Wound Therapy Systems: FDA Safety Communication. February 24, 2011. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm244211.htm. [Archived Content]

NPWT Home Use – Wound Types

Chronic Wounds: Defined for the purposes of this HTA by type or etiology and not by duration

- Venous leg ulcers (VLUs)
- Arterial leg ulcers
- Diabetic foot ulcers (DFUs)
- Pressure ulcers (PUs), and
- Mixed etiology chronic wounds

Surgical Wounds: Defined for this report as incisions made in the course of a patient's care for an underlying health concern requiring surgical intervention

- Primary intention: closed by means such as sutures, staples, tape, or glue that hold the wound edges together
- Secondary intention: left open for the healing process

Policy Context

- NPWT is used in the treatment of chronic or nonhealing wounds. Home use of NPWT includes use of a portable device.
- Agency concerns are considered medium for safety, medium/high for efficacy, and medium for cost-effectiveness.
- An evidence-based assessment of the comparative effectiveness, safety, and cost is warranted to guide coverage policy.

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Scope, Methods, and Search Results

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PICOS

- **Population:** Patients diagnosed with chronic wounds, defined specifically as VLUs, arterial leg ulcers, DFUs, PUs, and mixed etiology chronic wounds; or nonhealing surgical wounds (either closed or open)
- **Intervention:** Negative pressure wound therapy (NPWT)
- **Comparisons:** Other wound care methods; comparison of NPWT devices

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PICOS

- **Outcomes**
  - Clinical outcomes: Complete wound healing; time to complete wound healing; time to surgical readiness of the wound bed or time to wound closure; proportion of wounds closed; seroma/hematoma; reoperation; mortality; wound healing rate for healed wounds
  - Patient-centered outcomes: Return to prior level of functional activity; pain; health-related QOL
  - Safety: Infection rates; extremity amputation; emergency room visits related to the NPWT or treated wound; unplanned hospitalizations or surgeries related to the NPWT or treated wound; blood transfusions/bleeding
- **Setting:** Home or outpatient setting

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Key Questions

1. What is the clinical effectiveness of NPWT in the home or outpatient settings for treatment of:
   a. chronic wounds (i.e., VLUs, arterial leg ulcers, DFUs, PUs, and mixed etiology chronic wounds)?
   b. nonhealing closed or open surgical wounds (i.e., incisions expected to heal by primary intention or incisions expected to heal by secondary intention)?

2. What are the harms associated with NPWT?

3. Does the effectiveness of NPWT or incidence of adverse events vary by clinical history (e.g., diabetes), wound characteristics (e.g., size, chronicity), duration of treatment, types of devices, or patient characteristics (e.g., age, sex, prior treatments, smoking, or other medications)?

4. What are the cost implications and cost-effectiveness of NPWT?

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Search Strategy

- Systematic Reviews
  - AHRQ, Cochrane, Centre for Reviews and Dissemination
  - No date limit, searched on March 15, 2016, and May 11, 2016
- Identified eligible primary studies from selected systematic reviews
- Conducted update literature searches for additional primary studies
  - PubMed and Embase
  - Date limit: 12/1/2013 to 9/12/2016

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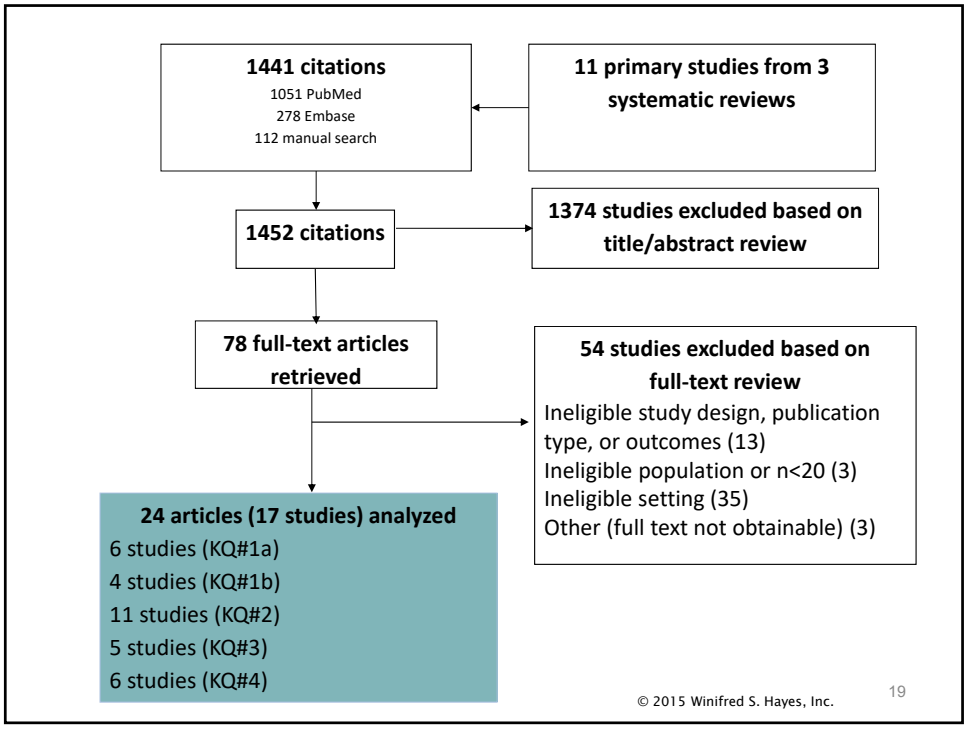

Quality assessment aligns with GRADE system

- Individual **study** appraisal
  - *Are the findings **valid**?*
    - Study design, execution, and analysis (checklist)
    - Internal validity (minimization of bias)
    - *Good–Fair–Poor–Very Poor*
- Evaluation of **body of evidence** for each outcome
  - *How **confident** are we that this evidence answers the Key Question?*
    - Domains:
      - –Study design and weaknesses
      - –Quantity/precision of data
      - –Publication bias
      - –Applicability to PICOS
      - –Consistency, study findings
    - *High–Moderate–Low–Very Low*

Findings

(See Summary of Findings Tables and Appendix V of the report for further detail)

KQ #1a Overview

Clinical Outcomes, Surgical Wounds

- For key question 1a regarding chronic wounds, the overall quality of evidence was considered to be **low**.
- 6 studies reported clinical or patient-centered outcomes for chronic wounds.
  - 2 RCTs
  - 4 Observational

KQ #1a Overview

Clinical Outcomes, Chronic Wounds

Wound type	KQ1a Outcome
DFUs (4 studies)	**Complete wound healing/closure** • Results from 3 studies [1 FQ RCT, 1 FQ cohort study, and 1 PQ cohort study] (n=3361) **Time to complete wound healing** • Results from 1 FQ RCT (n=342) **Pain** • Results from 1 PQ cohort study (n=1331)
PUs (2 studies)	**Complete wound healing** • Results from 2 studies [1 FQ RCT, 1 FQ cohort study] (n=364)

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KQ #1a Overview

Clinical Outcomes, Chronic Wounds

Wound type	KQ1a Outcome
VLUs (1 study)	**Complete wound healing** • Results from 1 FQ cohort study (n=342, includes patients with different types of lower extremity ulcers and/or multiple ulcers)
Arterial Ulcers (1 study)	**Complete wound healing** • Results from 1 FQ cohort study (n=342, includes patients with different types of lower extremity ulcers and/or multiple ulcers)
Mixed Etiology Ulcers (2 studies)	**Complete wound healing** • Results from 2 studies [1FQ cohort and 1 PQ cohort] (n=420) **Time to complete wound healing** • Results from 1 PQ cohort study (n=78)

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KQ #1a Diabetic Foot Ulcers

Studies (3)	Results – Complete wound healing/closure (n=3361)
Blume, 2008 (n=342, RCT, FQ) **Lavery, 2007** (n=2677, retrospective cohort, PQ) **Yao, 2012** (n=342*, retrospective cohort, FQ)	Blume, 2008 (mixed setting) Complete closure within ATP (≤112 days, n=335): NPWT 73/169 (43%); AMWT 48/166 (29%); *P*=0.007 Lavery, 2007 12 weeks (all): NPWT 39.5%; Controls 23.9%; *P*<0.001 20 weeks (all): NPWT 46.3%; Controls 32.8%; *P*<0.001 Yao, 2012 Incidence of wound healing; non-NPWT as reference group Adjusted HR: 3.26 (95% CI, 2.21-4.83) **Low Overall Quality for this outcome** (few studies, moderate to large sample size, mixed/uncertain applicability to PICOS, study quality poor to fair)

*Yao et al. (2012) studied 342 patients with various wounds; some patients may have had multiple wounds with different etiologies. The number of patients with DFUs = 258.

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KQ #1a Diabetic Foot Ulcers

Studies (1)	Results – Time to complete wound healing (n=342)
Blume, 2008 (n=342, RCT, FQ)	Blume, 2008 (mixed setting) 96 days (95% CI, 75.0-114.0) for NPWT and not determinable for AMWT (*P*=0.001) **Low Overall Quality** (1 FQ study, uncertain applicability to PICOS)
Studies (1)	**Results – Pain (n=1331)**
Fife, 2008 (n=1331, retrospective cohort, PQ)	Fife, 2008 Provision of pain medication as a surrogate measure for pain: *P*=NS **Very Low Overall Quality** (1 PQ study)

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KQ #1a Venous and Arterial Ulcers

Studies (1)	Results – Complete wound healing (n=342)
Yao, 2012 (n=342*, retrospective cohort, FQ)	Incidence of wound healing for arterial ulcers Non-NPWT as reference group Adjusted HR: 2.27 (95% CI, 1.56-3.78) Incidence of wound healing for venous ulcers Non-NPWT as reference group: Adjusted HR: 6.31 (95% CI, 1.49-26.6) **Very Low Overall Quality** (1 FQ study)

*Yao et al. (2012) studied 342 patients with various wounds; some patients may have had multiple wounds with different etiologies. The number of patients with arterial ulcers = 173, and venous ulcers = 33.

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KQ #1a Pressure Ulcers

Studies (2)	Results – Complete wound healing (n=364)
Ford, 2002 (n=22 pts, 35 wounds, RCT, FQ) **Yao, 2012** (n=342*, retrospective cohort, FQ)	Ford, 2007 (results analyzed per wound) NPWT 2/20 (10%); Control 2/15 (13%) (risk difference 3%; 95% CI, -18% to 25%) [calculated by Rhee et al., 2014] Yao, 2012 Incidence of wound healing for pressure ulcers Non-NPWT as reference group: Adjusted HR: 1.72 (95% CI, 0.43 to 6.95) **Very Low Overall Quality** (few studies, small sample sizes, mixed applicability to PICOS)

*Yao et al. (2012) studied 342 patients with various wounds; some patients may have had multiple wounds with different etiologies. The number of patients with pressure ulcers = 40.

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KQ #1a Mixed Etiology Ulcers

Studies (2)	Results – Complete wound healing (n=420)
Lerman, 2010 (n=78, cohort, PQ) **Yao, 2012** (n=342, retrospective cohort, FQ)	Lerman, 2010 (NPWT, Control) 1 month: 0%, 0%; 2 months: 20%, 7.1%; 3 months: 66.2%, 21.4% 4 months: 83.1%, 35.7% (statistical significance NR) Yao, 2012 Incidence of wound healing for mixed ulcers Non-NPWT as reference group: Adjusted HR: 2.63 (95% CI, 1.87–3.70) **Low Overall Quality** (few studies, small sample sizes, mixed applicability to PICOS, study quality poor to fair)
Studies (1)	**Results – Time to complete wound healing (n=78)**
Lerman, 2010 (n=78, cohort, PQ)	Lerman, 2010 Time to complete wound healing (mean ± SD), days: NPWT, Control (analysis based on patients with healed wounds): 74.25±20.1; 148.73±63.1 (P<0.0001), represents 50% absolute reduction in time to healing **Very Low Overall Quality** (1 PQ study)

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KQ #1b Overview

Clinical Outcomes, Surgical Wounds

- Four RCTs reported clinical or patient-centered outcomes for surgical wounds.
- The overall quality of the evidence for the clinical effectiveness of NPWT in the home or outpatient settings for treatment of surgical wounds healing by secondary intention is considered to be **low**. With respect to surgical wounds healing by primary intention, the evidence is **insufficient** based on 1 small RCT.
- Evidence was limited to 1 study each for 4 different surgical procedures, which may limit the applicability to other types of surgery.

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KQ #1b Clinical Outcomes

Studies (1)	Results – Complete wound healing (n=162)
Armstrong, 2005 (n=162, RCT, FQ) Partial diabetic foot amputation	Armstrong, 2005 (NPWT, Std tx) Proportion of wounds healed: 43 (56%), 33 (39%); *P*=0.04 **Very Low Overall Quality** (1 FQ study)
Studies (3)	**Results – Time to complete wound healing (n=231)**
Armstrong, 2005 (n=162, RCT, FQ) Partial diabetic foot amputation **Monsen, 2014** (n=20, RCT, FQ) Perivascular groin infections **Biter, 2014** (n=49, RCT, FQ) Pilonidal sinus disease	Armstrong, 2005 (NPWT, Std tx) Median (IQR), days: 56 (26–92), 77 (40–112); *P*=0.005 Monsen, 2014 (NPWT, Alginate dressing) Median (range) days: 57 (25–115) (for n=9); 104 (57–175) (for n=7); *P*=0.026 Biter, 2014 (NPWT, Silicone dressing) Median (range) days: 84 (34–349), 93 (43–264); *P*=0.44 **Low Overall Quality** (few studies, small sample sizes)

KQ #1b Patient-Centered Outcomes

Studies (2)	Results – Pain (n=69)
Monsen, 2014 (n=20, RCT, FQ) Perivascular groin infections **Biter, 2014** (n=49, RCT, FQ) Pilonidal sinus disease	Biter, 2014 (NPWT, Silicone dressing) VAS, median, day of surgery: 1.5; 1.7; *P*=0.24 VAS, median, 14 days after surgery: 2.2; 2.5; *P*=0.29 Monsen, 2014 (n=20 at study start, n=17 at 4 weeks) No difference in pain intensity or influence on daily life at study start or after 4 weeks of tx. **Very Low Overall Quality** (few studies, small sample sizes)
Studies (1)	**Results – Return to prior level of activity (n=49)**
Biter, 2014 (n=49, RCT, FQ) Pilonidal sinus disease	Biter, 2014 (NPWT, Silicone dressing) Time to return to work or school (median [range]), days: 27 (7–126); 29 (6–63); *P*=0.92 **Very Low Overall Quality** (1 FQ study)
Studies (2)	**Results – QOL (n=41)**
Monsen, 2014 (n=20, RCT, FQ) Perivascular groin infections **Manoharan, 2015** (n=21 pts, 42 knees, RCT FQ) Total knee arthroplasty	Monsen, 2014 suggests no difference Manoharan, 2015 reported significant differences in favor of NPWT for dressing leakage and wound protection, and no difference for other QOL indicators **Very Low Overall Quality** (few studies, small sample sizes)

KQ #2: Safety

- 6 studies (2 RCTs and 4 observational) reported on AEs in patients with chronic wounds
- 5 RCTs reported AEs in patients with surgical wounds
- The overall body of evidence for harms associated with home use of NPWT for chronic or surgical wounds is considered to be **low**

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KQ #2: Safety, Chronic Wounds, DFUs

AEs (studies)	Results
Amputation (n=2)	Blume, 2008: FQ RCT (n=335, DFUs) Favored NPWT (4% vs 10%; *P*=0.035) Frykberg, 2007: FQ obs (n=16,319, DFUs) Overall, NS differences without stratification or risk adjustment
Infection (n=2)	Fife, 2008: PQ obs (n=1331, DFUs) Favored NPWT (V.A.C. pts had fewer antibiotic prescriptions; *P*<0.05) Blume, 2008: FQ RCT (n=335, DFUs) No significant difference (NPWT 2% vs AMWT <1%)
Bleeding (n=1)	Fife, 2008: PQ obs (n=1331, DFUs) No NPWT pts discontinued because of bleeding; 0 cases of sanguineous drainage in either group
Edema (n=1)	Blume, 2008: FQ RCT (n=335, DFUs) No significant difference (NPWT 3% vs AMWT 4%)

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KQ #2: Safety, Chronic Wounds, PUs and Mixed

AEs (studies)	Results
Amputation (n=1)	Ford, 2002: FQ RCT (n=28, PUs) 1 in NPWT group vs 0 in comparison group (*P*=NR)
Infection (n=2)	Ford, 2002: FQ RCT (n=28, PUs) 1 case of sepsis in NPWT group vs 0 in comparison group; *P*=NR Lerman, 2010: PQ obs (n=78, mixed ulcers) 1 case of wound infection in NPWT group, AEs not reported for comparison group
ER Visits (n=1)	Schwien, 2005: PQ obs (n=2348, PUs) 0% in NPWT group vs 8% in comparison group; *P*<0.01
Hospitalization (n=1)	Schwien, 2005: PQ obs (n=2348, PUs) 5% in NPWT group vs 14% in comparison group; *P*<0.01

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KQ #2: Safety, Chronic Wounds

PUs and Mixed (cont'd)

- Other AEs reported (Lerman, 2010)
  - 1 obs study (n=78), NPWT patients with complications related to the study protocol requiring withdrawal: allergic skin reaction to the hydrocolloid dressing (n=1), bleeding post debridement (n=1), worsening lower extremity edema (n=1), and maceration to periwound skin (n=3)
  - AEs not reported for comparison group

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KQ #2: Safety, Surgical Wounds

AEs (studies)	Results
Amputation (n=2)	Armstrong, 2005: FQ RCT (n=162) NPWT 3% vs Std tx 11%; *P*=0.060; RR 0.225 (95% CI, 0.05-1.1) Monsen, 2014: FQ RCT (n=20) NPWT 3 (30%) vs Alginate 2 (20%); *P*=NR
Infection (n=4)	Armstrong, 2005: FQ RCT (n=162) NPWT 17% vs Std tx 6%; *P*=NR Biter, 2014: FQ RCT (n=49) NPWT 2 (8%) vs Silicone 2 (8%); *P*=1.00 Karlakki, 2016: FQ RCT (n=220) NPWT NR vs Control 7 (suspected); *P*=NR Manoharan, 2016: FQ RCT (n=21 pts; 42 knees) No wound dehiscence or infection in either group
Other (n=2)	Armstrong, 2005: FQ RCT (n=162) Treatment-related AEs: NPWT 9 (12%) vs Std Tx 11 (13%) Karlakki, 2016: FQ RCT (n=220) Overall wound complications: OR 4.0; 95% CI, 0.95-30; *P*=0.06

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KQ #2: Safety, Surgical Wounds

AEs (studies)	Results
Readmission (n=2)	Karlakki, 2016: FQ RCT (n=220) NPWT 0 vs Control 1; *P*=NR Manoharan, 2016: FQ RCT (n=21 pts; 42 knees) NPWT 1 vs Control 0; *P*=NR
Mortality (n=1)	Monsen, 2014: FQ RCT (n=20) NPWT 2 (20%) vs Alginate 5 (50%); *P*=0.35
Blisters (n=2)	Manoharan, 2016: FQ RCT (n=21 pts; 42 knees) NPWT 1 knee vs Control 0 Karlakki, 2016: FQ RCT (n=220) NPWT 11% vs Control 1%; *P*=NR

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KQ #3: Differential effectiveness or safety according to clinical history, patient characteristics, etc.?

- Overall, evidence of varying clinical effectiveness or rates of harms is considered to be **very low**
- 4 studies (1 RCT and 3 obs) of patients with chronic wounds
  - 2 compared different NPWT devices
  - 2 provide information about the role of wound size and chronicity
- 1 RCT of patients with surgical wounds
  - assessed the role of wound chronicity

KQ #3: Differential effectiveness or safety according to clinical history, patient characteristics, etc.?

SNaP Versus V.A.C.

Armstrong, 2011 and Marston, 2015 (1 FQ RCT, n=132, 16-week treatment period)

- Proportion of wounds healed: No statistically significant difference (*P*=0.96); analyses adjusting for baseline wound size and analyses among VLU patients only (n=40) were also not statistically significant.
- Agree or strongly agree that they were able to perform normal daily activities (n=105): Patients treated with SNaP device more likely than patients treated with V.A.C. device (79% and 58%, respectively).

KQ #3: Differential effectiveness or safety according to clinical history, patient characteristics, etc.?

SNaP Versus V.A.C. [cont'd]

- Activity level either increased or stayed the same: A higher percentage of SNaP-treated patients (83% vs 48%)
- Patient-reported pain scores: Not statistically significantly different
- Rates of AEs: Similar between the groups
- Infection: SNaP 2 (3.1%) vs V.A.C. 5 (7.4%) (P=0.28*)

*P value calculated by Rhee et al. (2014)

KQ #3: Differential effectiveness or safety according to clinical history, patient characteristics, etc.?

V.A.C. Versus non-KCI Models

Law, 2015 (1 PQ obs, n=13,556)

- Hospital readmissions
  - 3 months: V.A.C. 5% vs non-KCI 8% ($P \leq 0.01$)
  - 6 months: V.A.C. 6% vs non-KCI 11% ($P \leq 0.01$)
- Mean per-patient inpatient stays and ER visits at 3 months and 6 months (all wound types):
  - Significant differences in favor of V.A.C.

KQ #3: Differential effectiveness or safety according to clinical history, patient characteristics, etc.?

Wound size and chronicity

Lavery, 2007 (1 PQ obs, n=2677)

- DFUs (NPWT vs Std tx)
  - Wounds of all sizes treated with NPWT more likely than those treated with std tx to achieve successful treatment endpoint
  - At 12 weeks, wounds <6 months old or >12 months more likely to achieve closure with NPWT
  - At 20 weeks, wounds >12 months more likely to heal with NPWT ($P<0.05$)

KQ #3: Differential effectiveness or safety according to clinical history, patient characteristics, etc.?

Chronicity

Yao, 2014 (1 FQ obs, n=342)

- Mixed ulcers (early NPWT vs later NPWT)
  - Ulcers in early NPWT group had higher incidence of wound closure (adjusted HR, 3.38; 95% CI, 1.68–6.82)

KQ #3: Differential effectiveness or safety according to clinical history, patient characteristics, etc.?

Chronicity

Armstrong, 2005 & 2007

(1 FQ RCT, n=162, 16-week trial)

- Partial foot amputation in patients with diabetes (NPWT vs Std tx)
  - No statistically significant difference in proportion of acute (<30 days) and chronic (>30 days) wounds achieving complete closure (acute *P*=0.072; chronic *P*=0.320)
  - Time to complete closure was significantly different in favor of NPWT compared with the std tx for both acute (*P*=0.030) and chronic wounds (*P*=0.033)

KQ #4: Cost Implications

- 6 economic analyses
  - 1 study compared SNaP with electrically powered NPWT and std tx
  - 5 studies compared cost of V.A.C. with other wound treatments or other NPWT devices
  - All funded by device manufacturers
- Summary
  - All studies concluded that the primary NPWT device of interest (SNaP or V.A.C.) resulted in cost savings over usual care or alternative NPWT devices
- Limitations
  - Quality and applicability of evidence used for economic models

KQ #4: Cost Implications

Study Characteristics KQ #4	
Hutton and Sheehan, 2011 **Modeling** SNaP vs Std tx or electrically powered NPWT Funded by Spiracur.	• Costs were based on the literature comparing NPWT with modern dressings and Medicare reimbursement rates. • Costs of treatment included direct costs and other healthcare costs for diabetic lower extremity wounds.
Driver and Blume, 2014 **Post-hoc analysis of RCT** V.A.C. vs AMWT KCI employees provided data analyses and medical writing support; no financial support acknowledged.	• Data obtained from medical records of 324 (162 NPWT, 162 AMWT) patients with diabetic ulcers. • Wound treatment costs included dressings and labor costs to change dressings. • Nonwound therapy consisted of antibiotics, inpatient services, extended care hospitalizations, and surgical procedures.

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KQ #4: Cost Implications

Study Characteristics KQ #4	
Lavery, 2007 **Modeling** NPWT vs wet-to-moist tx KCI provided data; research sponsored in part by KCI.	• Cost of care in outpatient setting. • Calculations included probability of successful treatment in a specified number of weeks; estimate came from outcomes obtained from the observational study conducted by the authors and reported in the same publication.
Apelqvist, 2008 **Analysis of data from RCT** V.A.C. vs moist wound tx Funded by KCI.	• Diabetic pts with postamputation wounds. • Costs calculated retrospectively using data on resource use for each patient. • Costs included inpatient care, antimicrobial agents, outpatient visits, surgical procedures, and topical dressing treatment of foot ulcers. • Cost based on mean costs derived from a national commercial claims dataset.

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KQ #4: Cost Implications

Study Characteristics KQ #4	
Flack, 2008 **Modeling** V.A.C. vs traditional and advanced wound treatment Funded by KCI.	• Simulated population of patients with DFUs. • Selected trials provided effectiveness data. • Costs for traditional, advanced, and V.A.C. dressings obtained from reimbursement data and expert opinion. • Costs for antibiotics and utility weights for QALYs came from published literature. • Nondressing unit charges accounted for outpatient costs such as office visit and home health charges.
Law, 2015 **Claims database analysis** V.A.C. vs non-KCI models Funded by KCI.	• Patients who submitted claims for outpatient NPWT. • Chronic wounds comprised the majority of wounds (81%); acute wounds also assessed.

Practice Guidelines and Payer Policies

Payer Policies

- **Centers for Medicare & Medicaid Services (CMS)**
  - No CMS National Coverage Determination (NCD) for NPWT was identified. A Local Coverage Determination issued by Noridian Healthcare Solutions LLC was identified. See LCD for Negative Pressure Wound Therapy Pumps (L33821).
  - The LCD states that an NPWT pump and supplies are covered when ulcers and wounds are encountered in an inpatient setting or in the home setting when the criteria are met.
- **Aetna**
  - Considers NPWT pumps medically necessary for ulcers and wounds in an inpatient setting or in the home setting when the criteria are met. NPWT pumps and supplies are considered not medically necessary if any contraindication for use (as identified in the policy) is present. Aetna considers NPWT experimental and investigational for the treatment for some wounds and considers the use of some types of devices experimental and investigational.

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Payer Policies

- **Group Health Cooperative** – covers NPWT pumps and supplies for wound edema, exudate management, and stimulation of granulation for an initial 14-day course when:
  - the criteria are met for ulcers and wounds in an inpatient setting or in the home setting;
  - there is a goal of therapy clearly stated; and
  - there are no contraindications for use as identified in the policy.
- **Regence Group**
  - No published coverage policy for NPWT was identified on the Regence Group website.

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Payer Policies

- **Oregon Health Evidence Review Commission (HERC)**
  - No published coverage policy for NPWT was identified.
  - Guideline Note 62: "Negative pressure wound therapy (CPT 97605-97608, HCPCS G0456, G0457) is included on these lines only for patients who: have wounds that are refractory to or have failed standard therapies; are not suitable candidates for surgical wound closure; or, are at high risk for delayed or non-healing wounds due to factors such as compromised blood flow, diabetic complications, wounds with high risk of fecal contamination, extremely exudative wounds, and similar situations."
  - Oregon Medical Fee and Payment Rules (code E2402) provide a maximum limit for monthly rentals.

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5 Practice Guidelines	
International Expert Panel on Negative Pressure Wound Therapy (NPWT-EP) (2011)	• GLs do not mention setting of care. • GLs generally advise use of NPWT for PUs, DFUs, ischemic lower limb wounds, and VLUs to achieve specific treatment goals and under certain circumstances.
International Working Group on the Diabetic Foot (2016)	• GLs do not mention setting of care. • Topical NPWT may be considered in postoperative wounds, even though the effectiveness and cost-effectiveness of the approach remain to be established. • It is not possible to make a recommendation on the use of NPWT in nonsurgical wounds because of the lack of available evidence.
National Pressure Ulcer Advisory Panel (2014)	• GLs do not mention setting of care. • Consider NPWT as an early adjuvant for the treatment of deep, category/stage III and IV PUs.

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5 Practice Guidelines cont'd	
Association for the Advancement of Wound Care (2010)	• NPWT is described under the section "Advanced or adjunctive interventions if PU is unresponsive to A-level management." • GLs note that there is no consistent effect on PU healing; however, some evidence suggests that increased granulation, less fibrin compared with Redon drain, and earlier use may shorten home care stays. Also noted is that it may have a lower cost than gauze and the GLs mention the FDA advisory regarding selecting patients.
Society for Vascular Surgery and the American Venous Forum (2014)	• GL suggests against routine primary use of NPWT for VLUs.

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Overall Summary and Discussion

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Quality of the Body of Evidence

High
- Reliable evidence reflecting the true effect
- Unlikely to change with future studies

Moderate
- Reasonable confidence that the results represent the true direction of effect
- The effect estimate might change with future studies

Low
- Little confidence due to poor quality and/or mixed results and/or a paucity of studies
- Future studies are likely to change the estimates and possibly the direction

Very Low
- No confidence in any result found (e.g., paucity of data)
- Data are such that we cannot make a statement on the findings

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Summary: KQ1a, Chronic Wounds

- Results of the included studies were generally consistent for the few outcomes reported suggesting that NPWT may improve wound healing and time to wound healing compared with other wound treatments, particularly in relation to DFUs; however,
- The quality of the evidence was considered to be **low**
  - lack of evidence for some key outcomes, methodological limitations of available studies, few available studies for some types of chronic wounds, and obvious or potential heterogeneity within the body of evidence with respect to aspects such as treatment delivery, comparators, and methods.

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Summary: KQ1b, Surgical wounds

- Overall, the results favored NPWT for the clinical outcomes reported: complete wound healing (1 study) and time to complete wound healing (3 studies); however,
- The overall quality of the body of evidence was considered to be **low**.
  - Each of the 4 RCTs enrolled patients undergoing different surgical procedures and they compared different alternative wound therapies.

Summary: KQ2, Safety

- The quality of the overall body of evidence for harms associated with home use of NPWT for chronic wounds and surgical wounds is considered to be **low.**
- Chronic wounds
  - 6 studies of patients with DFUs, PUs, and mixed etiology ulcers
  - Studies suggest no difference in safety or favored NPWT
- Surgical wounds
  - 5 studies
  - Studies suggest no difference in safety or favored NPWT

Summary: KQ3, Varying clinical effectiveness or rates of harms

- Overall evidence from 5 studies is considered to be of **very low** quality.

Summary: KQ4, Economic analyses

- Economic analyses
  - Six studies were found that provided information about the cost of NPWT compared with usual care or other NPWT devices.
  - All studies found that the primary NPWT device of interest (SNaP or V.A.C.) resulted in cost savings over usual care or alternative NPWT devices.
  - All modeling studies were subject to the limitations of the evidence base.

Gaps in the Evidence

- Larger, more rigorous prospective studies conducted by independent researchers and designed to evaluate direct evidence of NPWT compared with consistent comparators for treatment of specific wound types in the home setting are needed.
- Consistent definitions and measurements for outcomes across studies would also be helpful.
- Publications with better reporting of study protocols, including settings and details about who changes wound dressings and details about interventions, comparators, and concomitant treatments are needed.
- Clear descriptions of inpatient and outpatient care would help identify studies applicable to the questions relevant to home use.
- There is a need for more studies examining response to treatment according to patient characteristics such as comorbidities, smoking status, and age.

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Thank you!

QUESTIONS?

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Washington State Health Care Authority
Health Technology Assessment

FINAL Key Questions and Background

Negative Pressure Wound Therapy (Home Use)

Background

Chronic wounds include venous ulcers, diabetic foot ulcers, and pressure sores, with causes that are related to venous insufficiency, pressure, diabetes, vascular disease, and immobilization. Although the causes for chronic wounds vary, in all cases, at least one of the phases of wound healing is compromised. Surgical wounds include clean, closed incisions expected to heal by primary intention as well as wounds that are left open to heal by secondary intention. Negative pressure wound therapy (NPWT), also referred to as subatmospheric pressure wound therapy or vacuum-assisted wound therapy, involves the application of subatmospheric pressure to an open wound with the goal of creating a controlled, closed wound amenable to surgical closure, grafting, or healing by secondary intention. NPWT has also been applied to closed surgical wounds that continue to drain after closure. NPWT is thought to promote wound healing by providing a warm, moist wound bed while removing wound fluid. This removes molecular factors that inhibit cell growth, improves blood flow to the wound, enhances wound oxygenation, and also improves the flow of nutrients to the wound. NPWT may also create mechanical forces that influence the wound macroscopically, by drawing the wound edges together, and microscopically, by exerting mechanical forces on tissue that induce cell proliferation, cell migration to the wound, and angiogenesis.

Policy Context

NPWT is used in the treatment of slow or non-healing wounds. Home use of NPWT includes use of a portable device in the home and/or outpatient setting. Concerns are considered medium for safety, medium/high for efficacy, and medium for cost-effectiveness.

Scope

Population: Patients diagnosed with chronic wounds (e.g., venous leg ulcers, arterial leg ulcers, diabetic foot ulcers, pressure ulcers, and mixed etiology chronic wounds) or non-healing surgical wounds

Interventions: Negative pressure wound therapy (NPWT)

Comparators: Other wound care methods; placebo; comparison of NPWT devices

Outcomes: Clinical outcomes (complete wound healing; time to complete wound healing; time to surgical readiness of the wound bed or time to wound closure; proportion of wounds closed; seroma/hematoma; re-operation; mortality; wound healing rate for healed wounds); patient-centered outcomes (return to prior level of functional activity; pain; health-related quality of life); safety (infection rates; extremity amputation; emergency room visits related to the NPWT or treated wound; unplanned hospitalizations or surgeries related to the NPWT or treated wound; blood transfusions/bleeding).

Settings: Home or outpatient setting.

Key Questions

1a. What is the clinical effectiveness of NPWT in the home or outpatient settings for treatment of chronic wounds (i.e., venous leg ulcers, arterial leg ulcers, diabetic foot ulcers, pressure ulcers, and mixed etiology chronic wounds)?

1b. What is the clinical effectiveness of NPWT in the home or outpatient settings for treatment of non-healing closed or open surgical wounds (i.e. incisions expected to heal by primary intention or incisions expected to heal by secondary intention)?

2. What are the harms associated with NPWT?

3. Does the effectiveness of NPWT or incidence of adverse events vary by clinical history (e.g., diabetes), wound characteristics (e.g., size, chronicity), duration of treatment, types of device, or patient characteristics (e.g., age, sex, prior treatments, smoking, or other medications)?

4. What are the cost implications and cost-effectiveness of NPWT?

Public Comment and Response

See Draft Key Questions: Comment and Response document published separately.

HTCC Coverage and Reimbursement Determination Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on three questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are evidence-based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards[2]:

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms[3]:

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.

[1] Based on Legislative mandate: See RCW 70.14.100(2).

[2] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

[3] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

Using evidence as the basis for a coverage decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. Availability of Evidence:

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. Sufficiency of the Evidence:

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- The amount of evidence (sparse to many number of evidence or events or individuals studied);
- Consistency of evidence (results vary or largely similar);
- Recency (timeliness of information);
- Directness of evidence (link between technology and outcome);
- Relevance of evidence (applicability to agency program and clients);
- Bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

3. Factors for Consideration - Importance

At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- Risk of event occurring;

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

- The degree of harm associated with risk;
- The number of risks; the burden of the condition;
- Burden untreated or treated with alternatives;
- The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- Value variation based on patient preference.

Clinical Committee Findings and Decisions

Efficacy Considerations

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value?
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy?
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices?

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
  - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
  - Adverse effect on health that can result in lasting harm or can be life-threatening?
- Other morbidity concerns?
- Short term or direct complication versus long term complications?
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost Impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives?
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?

Next Step: Cover or No Cover

If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover with Conditions

If covered with conditions, the Committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
    - Refer to evidence identification document and discussion.
    - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
    - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.

2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
    - What are the known conditions/criteria and evidence state
    - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Clinical Committee Evidence Votes

First Voting Question

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Discussion Document: What are the key factors and health outcomes and what evidence is there? (Applies to the population in the PICO for this review)

Safety Outcomes	Importance of Outcome	Safety Evidence / Confidence in Evidence
Amputation		
Infection		
Bleeding		
Edema		
Hospitalization		
Emergency Room (ER) visits		
Allergic skin reaction		
Readmission		
Mortality		
Blisters		

Efficacy – Effectiveness Outcomes	Importance of Outcome	Efficacy / Effectiveness Evidence
Complete wound healing		
Time to complete wound healing		
Pain		
Complete wound closure		
Return to prior activity level		
Quality of Life (QOL)		

Cost Outcomes	Importance of Outcome	Cost Evidence
Cost-effectiveness		
Direct costs		
Cost-savings		

Special Population / Considerations Outcomes	Importance of Outcome	Special Populations/ Considerations Evidence
Wound chronicity		
Wound size		
Device type		

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

For Safety: Is there sufficient evidence that the technology is safe for the indications considered?

Unproven (no)	Less (yes)	Equivalent (yes)	More in some (yes)	More in all

For Efficacy/Effectiveness: Is there sufficient evidence that the technology has a meaningful impact on patients and patient care?

Unproven (no)	Less (yes)	Equivalent (yes)	More in some (yes)	More in all

For Cost Outcomes/Cost-Effectiveness: Is there sufficient evidence that the technology is cost-effective for the indications considered?

Unproven (no)	Less (yes)	Equivalent (yes)	More in some (yes)	More in all

Discussion

Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second Vote

Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is

_____Not Covered _____ Covered Unconditionally _____ Covered Under Certain Conditions

Discussion Item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Next Step: Proposed Findings and Decision and Public Comment

At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

1) Based on public comment was evidence overlooked in the process that should be considered?

2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Next Step: Final Determination

Following review of the proposed findings and decision document and public comments:

Final Vote

Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no, or an unclear (i.e., tie) outcome Chair will lead discussion to determine next steps.

Medicare Coverage and Guidelines

[From page 22 of the Final Evidence Report]

No CMS National Coverage Determination (NCD) for NPWT was identified on July 25, 2016 (search National Coverage Documents by keywords *negative pressure* or *wound* or *ulcer* or *e2402* in all documents at: https://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx).

Guidelines

[From page 119 of the Final Evidence Report]

Key: DFU, diabetic foot ulcer; FDA, Food and Drug Administration; NPWT, negative pressure wound therapy; PU, pressure ulcer; VLU, venous leg ulcer

Sponsor, Title	Relevant Recommendations	Quality*/Main Limitations

International Expert Panel on Negative Pressure Wound Therapy (NPWT-EP) (Vig et al., 2011)
 	
Evidence-based recommendations for the use of NPWT in chronic wounds: steps towards an international consensus
	• PU
	  ○ NPWT may be used until surgical closure is possible/desirable.
	  ○ Alternatively, NPWT should be considered to achieve closure by secondary intention.
	  ○ NPWT should be used to reduce wound dimensions.
	  ○ NPWT should be used to improve the quality of the wound bed.
	• DFU
	  ○ NPWT must be considered as an advanced wound care therapy for postoperative Texas grade 2 and 3 diabetic feet without ischemia.
	  ○ NPWT must be considered to achieve healing by secondary intention.
	  ○ Alternatively, NPWT should be stopped when wound has progressed suitably to be closed by surgical means.
	  ○ NPWT should be considered in an attempt to prevent amputation or re-amputation.
	• Ischemic lower limb wounds
	  ○ The cautious use of NPWT in chronic limb ischemia when all other modalities have failed may be considered in specialist hands but never as an alternative for revascularization.
	  ○ NPWT may be considered as an advanced wound care therapy for lower limb ulceration after revascularization.
	  ○ The use of NPWT is NOT indicated in acute limb ischemia.
	• VLUs
	  ○ If first-line therapy (compression) is not efficacious, NPWT should be considered to prepare the wound for surgical closure as part of a clinical pathway.
	  ○ Use of gauze may be considered to reduce pain during dressing changes in susceptible patients.
		5.3 – Fair (more discussion of the strengths and limitations of body of evidence needed; the expert panel, literature review, and guideline development and writing was funded and led by Smith & Nephew; membership in the Expert Panel is not described; authors state that the manuscript was not unfairly influenced by the funder and that the recommendations reflect the independent and unbiased views of the expert panel)

Association for the Advancement of Wound Care (AAWC, 2010)	D. ADVANCED OR ADJUNCTIVE INTERVENTIONS IF PU IS UNRESPONSIVE TO A-LEVEL MANAGEMENT	4.0 – Fair (criteria for selecting evidence not described, methods for formulating recommendations

Sponsor, Title	Relevant Recommendations	Quality*/Main Limitations
Association for the Advancement of Wound Care (AAWC) Guideline of Pressure Ulcer Guidelines	3. Negative Pressure Wound Therapy—No consistent effect on PU healing. Increased granulation, less fibrin compared to Redon drain, earlier use may shorten home care stays. Lower cost than gauze. The FDA has advised caution in selecting patients for this therapy due to serious, occasionally fatal, complications. Please read the FDA notice at: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm190658.htm	not described, guideline review and update process not described)
National Pressure Ulcer Advisory Panel (NPUAP, 2014) *Treatment of pressure ulcers. In: Prevention and treatment of pressure ulcers: clinical practice guideline*	NPWT 1. Consider NPWT as an early adjuvant for the treatment of deep, category/stage III and IV pressure ulcers. (Strength of Evidence = B; Strength of Recommendation = Weak positive recommendation) *Caution: NPWT is not recommended in inadequately debrided, necrotic or malignant wounds; where vital organs are exposed; in wounds with no exudate; or in individuals with untreated coagulopathy, osteomyelitis or local or systemic clinical infection. Cautious use by an experienced health professional is recommended for individuals on anticoagulant therapy; in actively bleeding wounds; or where the wound is in close proximity to major blood vessels.* 2. Debride the PU of necrotic tissue prior to the use of NPWT. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation) 3. Follow a safe regimen in applying and removing the NPWT system. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation) 4. Evaluate the PU with each dressing change. (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation) 5. If pain is anticipated or reported consider: 1. Placing a nonadherent interface dressing on the wound bed, underneath the foam 2. Lowering the level of pressure, and/or changing type of pressure (continuous or intermittent) 3. Using a moist gauze filler instead of foam (Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation) 6. Educate the individual and his/her significant others about NPWT when used in the community setting. (Strength of Evidence = C; Strength of Recommendation = Strong positive recommendation)	6.4 – Good (procedure for updating not identified)

Sponsor, Title	Relevant Recommendations	Quality*/Main Limitations
International Working Group on the Diabetic Foot (Game et al., 2016) *IWGDF guidance on use of interventions to enhance the healing of chronic ulcers of the foot in diabetes*	Topical NPWT may be considered in postoperative wounds even though the effectiveness and cost-effectiveness of the approach remain to be established. (weak; moderate) It is not possible to make a recommendation on the use of NPWT in nonsurgical wounds because of the lack of available evidence.	6 – Good (unclear if guidelines were reviewed externally by experts, a procedure for updating was not identified)
Society for Vascular Surgery (SVS) and the American Venous Forum (AVF) (O'Donnell et al., 2014) *Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum*	Guideline 4.24: Negative Pressure Therapy [–] We suggest against routine primary use of negative pressure wound therapy for venous leg ulcers. [GRADE - 2; LEVEL OF EVIDENCE - C] There is currently not enough information to support the primary use of NPWT for VLUs. Evidence supports positive effects with the use of negative pressure therapy for wound healing in general. Tissue granulation, area and volume reduction, and reductions in bioburden have all been reported. There have been few studies specifically studying negative pressure therapy for VLUs, with most studies reporting on mixed wound causes. There has been an increase in the use of NPWT for wound bed preparation to augment skin graft healing.	6.2 – Good (criteria for selecting evidence is not clearly described; need to update mentioned, but the method for updating was not identified)