#### BEFORE THE ALASKA OFFICE OF ADMINISTRATIVE HEARINGS

In the Matter of	)	
	)	
GARY C. NEWMAN	)	OAH No. 14-2006-PER
	)	Agency No. 2014-1104

# Newman List of Exhibits Amended Feb. 5, 2015

#### A. Medical Necessity

- 1. Medical Necessity Letter from Dr. Charles Steiner, Tanana Valley Clinic, Fairbanks, AK GP to Gary Newman
- 2. Medical Necessity Letter from Dr. Danny Robinette, Northern Alaska Medical Surgery, gastroesophageal surgeon and practitioner - referring surgeon
- 3. Medical Necessity Letter from Dr. John Lipham, USC Keck Medical Center, surgeon, researcher, and expert in LINX procedure and gastro-esophageal issues

#### **B.** Plan and Appeal Approvals

- Medicare-Medicaid LINX coding and billing guide (verifying procedure coverage)

  effective 1/1/2014
- 2. Aetna approval for City of Seattle employee
- 3. City of Seattle Health Care Plan administered by Aetna
- 4. TakeCare approval letter for LINX procedure and accompanying plan document related to Exceptions
- 5. Presbyterian Medical Policy, NM, on LINX
- 6. Fowler-White-Boggs (employer) approval directive
- 7. State of Michigan BCBSM appeal granted Feb. 10,2014
- 8. State of Michigan Priority Health appeal granted April 8, 2014
- 9. State of Michigan BCBSM appeal granted May 20, 2014
- 10. MMro (external independent review) BCBS Wisconsin LINX appeal granted Nov. 2014
- 11. California LINX appeals granted
- 12. Government of Guam approval with copy of plan relating to exclusions

## C. FDA Approval

- 1. FDA approval noted 'continued safety and effectiveness'
- 2. FDA Summary of Safety and Effectiveness Data
- 3. FDA Expert Review Panel 01-11-12 Transcript (which led to approval)
- 4. FDA Expert Review Panel Transcript slides
- 5. FDA regs. CFR-2014-title21-Vol8-Part 814

#### D. Medical Research Studies

- 1. Annals of Thoracic Surgery-04-2014-Louie-et.al.-Linx-Nissen comparison
- 2. Int'l Society for Diseases of the Esophagus Journal-1000 patient-Safety-Lipham, et. al. 2014
- 3. Surgical Endoscopy-Lipham, et.al. March 2012-Confirmed safety and efficacy at 4 years
- 4. Journal of the American College of Surgeons Bonavina 1013-100 patients-6 years
- 5. NE Journal of Medicine-Ganz-02-21-2013-Prospective-3 of 5 years\_Pivotal Data
- 6. Surgical Endoscopy-Riegler, et.al. Aug. 2014 LINX-Nissen 1 year prospective study
- 7. American Surgeon-Reynolds, et.al. Oct. 2014 MSA with LINX 67 patients
- 8. PR\_Torax\_5YearPivotalData (continuation of Ganz 02-21-2013 final report in print is not yet available see Evidence Pending Availability below)
- 9. SAGE-Bonavina- LINX Reflux Management System in chronic gastroesophageal reflux-2013
- 10. Torax-Smith and Louie (LINX-NF comparison) Press Release-07011
- 11. Torax-Riegler\_Press\_Release\_LINX-NF comparison

#### E. Media

- 1. Dr. Lipham GERD presentation
- 2. LinxforLife.com website link
- 3. LinxforLife.com video
- 4. Video presentation on WUSA 072813 2:00
- 5. Video presentation of Atlanta 11alive interview on Linx 6:58
- 6. Video presentation of AP Report 041113 1:33
- 7. Video of LINX surgical procedure 9:14
- 8. Video of UC San Diego LINX implantation 2012
- 9. Video presentation of Nissen Fundoplication procedure
- 10. Medications hands-on display (to be presented at hearing)

#### F. Other

- 1. List of Torax LINX Implantation Certified Centers and Surgeons
- 2. LINX Reflux Management System Instructions for Use

### **G.** Travel and Expenses

- 1. USC Keck Hospital billing
- 2. Email from Dr. Lipham's Operations Manager re Dr. Lipham and USC Keck charges
- 3. Travel costs Alaska Air FAI-LAX
- 4. Travel costs Alaska Air LAX-FAI
- 5. Newman e-chat with Andrea-Aetna re travel coverage

### H. Already offered in Record of Appeal provided by the State

- 1. P.19-21 Aetna approval letter for LINX procedure for patient 1 Denmar 7/16/2013
- 2. P. 22-24 Aetna approval letter for LINX procedure for patient 2 Denmar 7/16/2013
- 3. P 25-28 Aetna approval letter for LINX procedure for patient 3 Stiffel Financial 5/16/2014
- 4. P 29-31 Aetna approval letter for LINX procedure for patient 4 Hilti 7/16/2013

5. P 31-36 State of Michigan Dept. of Insurance and Financial Services – 5/21/14

## I. Exhibits pending availability

- 1. CPT code established for LINX
- 2. Abstract for 5 Year Pivotal Data study, announced Oct. 2014

All exhibits already provided in the record of appeal provided by the Division of Retirement Benefits

DATED this 5th day of February, 2015.



Gary C. Newman, Appellant

The undersigned certifies that on Feb. 5, 2015, this Amended List of Exhibits was emailed to the following: Judge Stephen C. Slotnick, Office of Administrative Hearings, <a href="mailto:doa.oah@alaska.gov">doa.oah@alaska.gov</a>; Assistant Attorney General Joan Wilkerson, Alaska Dept. of Law <a href="mailto:joan.wilkerson@alaska.edu">joan.wilkerson@alaska.edu</a>

