



Health Technology Clinical Committee

Date: August 24, 2007

Time: 8:00 am – 4:30 pm

Location: Marriott Hotel – 3201 South 176th Street, Seattle, WA 98188

Teleconference Bridge: 360-923-2997 Access Code: 360-946-1464

HTCC MINUTES

Members Present: Brian Budenholzer; C. Craig Blackmore; Michael Myint; Carson Odegard; Daniel Abrahamson; Richard Phillips; Michelle Simon and Michael Souter

Telephonic: Louise Kaplan

Members Absent: Lydia Bartholomew

HTCC Formal Action

- ✓ **Call to Order:** Dr. Budenholzer, Chair, called the meeting to order at 8:05 a.m. Sufficient members were present to constitute a quorum.
- ✓ **May 18, 2007 Minutes:** Dr. Budenholzer referred members to the draft minutes and called for discussion or objection, and received none.
 - *Outcome:* The committee unanimously approved the May 18, 2007 minutes.
- ✓ **Pediatric Bariatric Surgery Coverage Determination:** The HTCC reviewed and considered the Bariatric Surgery in Pediatric Patients technology assessment report, information provided by the Administrator, agency comments, ECRI Institute's presentation; and invited public testimony. The committee considered all the evidence and has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.
 - *Outcome:* The committee unanimously voted that Pediatric Bariatric Surgery for patients under age 18 is not a covered benefit due to insufficient evidence to conclude that it is safe, efficacious, and cost-effective.
 - *Outcome:* The committee decided by a majority vote that Pediatric Bariatric Surgery for patients aged 18 - 20 years is a covered benefit only under certain criteria:
 - Bariatric surgical procedure of Laparoscopic adjustable gastric banding only
 - Patients must meet and abide by all other agency bariatric surgery program criteria (e.g. body mass index, presence of co-morbid condition(s), pre-surgical weight loss, specified centers or practitioners)

For presentation and discussion details, please see following pages

Final Official Version

HTCC MEETING TOPICS, PRESENTATION, AND DISCUSSION

Agenda Item: Welcome & Introductions

Brian Budenholzer, Committee Chair, and Leah Hole-Curry, HTA Program Director, opened the meeting with an overview of the agenda, meeting purpose and introductions.

- ✓ The Health Technology Clinical Committee (HTCC) met on August 24, 2007, to discuss the evidence of Pediatric Bariatric surgery; hear ECRI Institute's presentation and public comment; approve the May 18, 2007 public meeting minutes; and determine a coverage determination based on the evidence regarding if the technology is safe, efficacious and cost-effective.
 - *Outcome:* Informational meeting context

Agenda Item: HTA Program Update

Leah Hole-Curry, HTA Program Director, presented an HTA program update

- ✓ HTA Goal: Achieve better health by paying for technologies that work.
 - Maintain an open and transparent process; eliminate bias; promote consistency; and remain flexible by reviewing evidence regularly to ensure updated information is included.
 - The purpose of the committee is to make coverage determinations for the participating agencies (Health Care Authority; Department of Social and Health Services; and Labor and Industries) based on a health technology assessment presented by Spectrum Research, Inc. that reviews the scientific evidence of the relative safety, efficacy, and cost; information from any special advisory groups; and their professional knowledge and expertise.
 - Key focus questions: Is it safe? Is it effective? Does it provide value?
- ✓ Program Progress: Current technologies under review
 - 3 topics selected in January 2007
 - Upright MRI: Clinical committee decision of no coverage in May 2007. Agencies have implemented coverage change (July 2007).
 - Pediatric Bariatric Surgery: committee decisions pending today.
 - Lumbar Fusion and discography: Report due September, 2007; public meeting for discussion scheduled for November 16, 2007.
- ✓ Coverage Determination Process:
 - As defined in the WAC when making a coverage determination, committee members shall review and consider the health technology assessment. The committee may also consider other information it deems relevant, including other information provided by the administrator, reports and/or testimony from an advisory group, and submission or comments from the public.
 - HCA Administrator selects technology → Vendor produce Technology Assessment Report → Clinical committee makes coverage determination → Agencies implement decision (unless statutory conflict).

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- The committee shall give the greatest weight to the evidence determined, based on objective factors, to be the most valid and reliable, considering the nature and source of the evidence, the empirical characteristic of the studies or trials upon which the evidence is based, and the consistency of the outcome with comparable studies. The committee may also consider additional evidentiary valuation factors such as recency (date of information); relevance (the applicability of the information to the key questions presented or participating agency programs and clients); and bias (presence of conflict of interest or political considerations).
 - *Outcome:* Informational context

Agenda Item: Topic Selection and Introduction

Leah Hole-Curry, HTA Program Director, introduced the technology selection process and the Pediatric Bariatric surgery topic.

- ✓ Technology Selection Process: The Administrator, in consultation with participating agencies and the committee, shall select the health technologies to be reviewed by the committee under RCW 70.14.110. Up to six technologies may be selected for review in the first year, and up to eight may be selected in the second year. In making the selection, priority shall be given to any technology for which: (a) There are concerns about its safety, efficacy, or cost-effectiveness, especially relative to existing alternatives, or significant variations in its use; (b) Actual or expected state expenditures are high, due to demand for the technology, its cost, or both; and (c) There is adequate evidence available to conduct the complete review.
 - Primary Criteria
 - Patient harm or safety concerns
 - Concerns about therapeutic efficacy or diagnostic accuracy and appropriateness of outcomes for patients
 - Cost impact for state purchasing agencies
 - Secondary Criteria
 - Number of persons affected
 - Severity of condition
 - Policy related urgency / diffusion concern
 - Potential or observed variation in care
 - Special populations or ethical concerns
 - *Note:* Key questions for this technology posted on HTA website: <http://www.hta.hca.wa.gov/docs/bariatric.pdf>
- ✓ Pediatric Bariatric surgery is intended to resolve co-morbid conditions linked to obesity (e.g., hypertension, diabetes type II) through weight loss. Many different types of bariatric surgical procedures are performed, so “bariatric surgery” cannot be considered a single procedure. Some Bariatric surgeries are purely restrictive – they cause weight loss by limiting the amount of food that can be consumed in one meal. Others are malabsorptive – they cause weight loss by reducing the amount of food that is absorbed into the body. The two most common Bariatric surgical procedures are laparoscopic adjustable gastric banding (LAGB), which is a purely restrictive procedure, and Roux-en-Y gastric bypass (RYGB), which is both restrictive and malabsorptive. While the mechanism of action differs from procedure to procedure, all Bariatric

procedures are intended to induce weight loss, improve medical co-morbidities, enhance quality of life, and (ultimately) extend survival.

- ✓ Current alternatives to LABG and RYGB for pediatric patients include: dietary modification, increasing physical activity and exercise, behavioral modification, and pharmacotherapy. The potential advantage of pediatric bariatric surgery is that with weight loss, altered perception of body image, depression and social stigmatization as well as co-morbid conditions may decrease.
- ✓ The potential advantage of pediatric bariatric surgery is that surgically limiting caloric intake can more effectively result in clinically significant weight loss. Sustained and significant weight loss improves or eliminates co-morbid conditions, body image, depression, and social stigmatization. Current alternatives are not as effective at weight loss and comparisons with other treatments for the co-morbid conditions aren't available.
- ✓ Potential risks of bariatric surgery include: failure of surgery to produce weight loss, patient compliance with required post-operative instructions and diet, complications requiring re-operation, intolerable side-effects resulting in revision/conversion surgery. Common surgical complications (infection, shock, peri/post operative bleeding, and death); procedure specific complications (band slippage, stomach erosion, port/tubing problems, pouch dilation, stomal stenosis, staple line disruption, internal hernia, cholestyctomy, gastrointestinal obstructions) and other complications including malnutrition, dumping syndrome, ulcers.
- ✓ The potential impact on the health system is unknown. Potential benefits include a reduction or elimination of obesity related health care disease burden and future cost savings related to prevention or alleviation of co-morbidities. The potential burden includes the initial intensity of the intervention on health care resources and patient, cost of surgery and pre and post operative care; costs and burden of surgical complications; and long term maintenance for implanted devices.

➤ *Outcome:* Informational context for technology under consideration.

Agenda Item: New Technologies Selected

Leah Hole-Curry, HTA Program Director, reported on the technologies selected by the administrator.

- ✓ On August 23rd, HCA Administrator Steve Hill, selected a new round of technologies to undergo review. Six technologies were selected based on the process and criteria identified previously:
- ✓ New selected technologies will be published to the website on Monday August 27, 2007 for a 30 day comment period. Work plans will be drafted and an update with timelines will be given for each of the technologies.
 - Cardiac Stent (Off Label usage)
 - Artificial Discs
 - Arthroscopic Surgery of the Knee
 - Computed Tomographic Angiography (CTA for cardiac care)
 - Virtual Colonoscopy (CTC)
 - Intrathecal Pump (Chronic non-cancer pain management)

Agenda Item: Technology Assessment Presentation

Jonathan Treadwell, Ph.D., and Karen Schoelles, M.D., S.M, from ECRI Institute presented a summary of the technology assessment report.

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- ✓ Pediatric population is defined as patients aged 21 or younger, corresponding to the definition of the American Association of Pediatrics.
 - ✓ Recent years have seen substantial increases in the prevalence of morbid obesity in both the adult and pediatric populations. Between 1988 and 1994, 2.9% of adults in the United States were morbidly obese; this percentage rose to 4.9% (10.8 million people) between 1999 and 2002. The condition was more common among women (6.4%) than among men (3.3%).
 - ✓ Studies in pediatric populations have demonstrated the health risks of obesity in pediatric populations, and that obesity during adolescence is highly likely to persist into adulthood and create greater risks of adult health problems. Pediatric obesity may also be associated with reduced quality-of-life and social marginalization. Obese individuals are at increased risk of type 2 diabetes, hypertension, coronary artery disease, stroke, gallbladder disease (cholelithiasis), osteoarthritis, sleep apnea, respiratory problems, and many types of cancer (including endometrial, breast, prostate, and colon). These health risks contribute to obesity-related increases in all-cause mortality.
 - ✓ Medical intervention for obesity is intended to promote weight loss and thereby reduce co-morbid conditions associated with excess weight. Categories of treatment include diet, exercise, behavioral modifications, pharmacotherapy, and bariatric surgery.
 - ✓ The goal of bariatric surgery in pediatric patients with morbid obesity is to halt the progression of obesity into adulthood to improve or eliminate medical conditions associated with obesity, and to improve the quality of life. Use of bariatric surgery to treat morbid obesity has increased dramatically in recent years, from approximately 13,000 operations in 1998 to approximately 121,000 operations in 2004. Patients under age 18 comprise about 0.1 – 1% of patients reported to have received bariatric surgery for morbid obesity.
 - ✓ Included studies: based on systematic review of the literature, 153 abstracts were identified – 38 articles were retrieved, 14 of these articles were excluded because they did not meet the inclusion criteria. After these exclusions, 17 unique studies in 24 publications comprised the evidence base. Eight studies reported outcomes after laparoscopic adjustable gastric banding (LAGB), six after Roux-en-Y gastric bypass (RYGB), two after vertical banded gastroplasty (VBG), and one after banded bypass.
 - ✓ Assessment of Overall Strength of Evidence
 - Key Question #1: Strength of evidence was weak in concluding that LAGB and RYGB for morbidly obese patients aged 21 or less does lead to sustained and clinically significant weight loss compared to non-operative approaches. The evidence is insufficient to permit quantitative estimates of the precise amount of weight loss after any bariatric surgical procedure for pediatric patients.
 - Key Question #2: Strength of evidence was weak in concluding that LAGB and RYGB for morbidly obese patients aged 21 or less resolves co-morbid conditions linked to obesity (diabetes, hypertension) compared to non-operative approaches. The evidence is insufficient to permit quantitative estimates of the likelihood of co-morbidity resolution, quality of life, or survival after any bariatric surgical procedure for pediatric patients.
 - Key Question #3: The review of 8 LAGB studies found no reported in-hospital or postoperative death; the most frequently reported complication after LAGB was band slippage; re-operations were performed on 26 (7.92%) of the 328 LAGB patients to correct various complications. The review of 6 RYGB studies found one reported postoperative death for RYGB; no in-hospital death was reported; the most frequently reported

complication was related to protein-calorie malnutrition and micronutrient deficiency; and potentially life-threatening complications were reported in the RYGB studies. The evidence is insufficient to permit any conclusions on potential harms in specific age surgery on growth and development of pediatric patients.

- Key Question #4: Nationally, the median inpatient hospital cost for bariatric surgeries performed in pediatric patients in 2004 was \$8,651; the median hospital charge was \$25,021. Nationally, the median inpatient hospital cost for restrictive bariatric procedures performed in pediatric patients in 2004 was \$6,688; the median inpatient hospital cost for bypass procedures was \$8,893. Nationally, for those aged 13-17, the median inpatient hospital cost for bariatric procedures performed in 2004 was \$7,973; the median inpatient hospital cost for those aged 18-21 was \$8,945. No conclusions can be drawn regarding the cost of patients aged 12 and under due to lack of data. The evidence was not sufficient to permit the development of a comprehensive cost profile of non-operative approaches to pediatric obesity management.
- Key Question #5: The evidence is insufficient to permit any conclusion that the effectiveness, safety and cost of bariatric surgery for patients varies based on patients' characteristics, including: chronological age; physiologic/skeletal age; pre-surgical BMI; pre-surgical BMI categories; sex; race; co-morbid conditions (e.g., hypertension); and other factors (e.g., psychosocial or socioeconomic factors).

Evidence-Based Summary and Conclusions

- ✓ The potential benefits of LAGB and RYGB for pediatric patients with morbid obesity are the substantial weight loss (key question 1) and the resolution of medical conditions associated with obesity (key question 2). The limited evidence available suggests these potential benefits in pediatric populations; however, direct evidence on enhanced quality of life and extended long term survival is too sparse (or simply unavailable) to support conclusions. Also, current evidence does not permit conclusions about whether certain patient characteristics (e.g., age, sex, pre-surgical BMI) are predictive of surgical outcomes (key question 5).
- ✓ The potential benefits of bariatric surgery must be weighed against the complications (key question 3). For LAGB, the primary concern is the need for re-operation to correct problems associated with the band and port. Reasons for re-operation include band slippage, intragastric migration, and port/tubing problems. For RYGB, there is a different profile of complications, varying from mild events (e.g., slight malnutrition, correctable by supplements) to severe events (e.g., pulmonary embolism, severe malnutrition, immediate postoperative bleeding, digestive obstruction, staple line leak). Precisely how often these events occur in pediatric patients is unknowable, due to the sparseness of the evidence.
- ✓ The costs associated with bariatric surgery (key question 4) include not only the hospital inpatient costs of the procedure, but also the costs for professional services and postoperative management. No published data exists covering all such costs for bariatric surgery in pediatric patients.
- ✓ Future research on the use of bariatric surgery should be performed to provide greater clarity about bariatric risks and benefits in the pediatric population. Longer follow-up in prospective studies of larger populations could provide insights into key issues of informed consent, compliance with post-surgical regimens, the impact on physical growth, influence on medical co-morbidities, quality of life, and long-term survival.

➤ *Outcome:* Technology Assessment Report Findings



Agenda Item: Public Comments

- ✓ Allergan provided an industry comment
- ✓ No other public members signed up or made public comments.

Agenda Item: HTCC Decision Tool

Brian Budenholzer, Chair, and the committee used the decision worksheet in evaluating the evidence of the technologies’ safety, efficacy, and cost effectiveness. The tool was a combination of efforts based on staff, committee input and Dr. Budenholzer’s research, it was refined after the first committee meeting based on input of the committee. Committee members use the worksheet to assist them in their discussion and evaluation of the technology.

Agenda Item: HTCC Pediatric Bariatric Surgery Technology Decision

Brian Budenholzer, Committee Chair, led a discussion of the evidence related to the safety, efficacy, and cost effectiveness of Pediatric Bariatric surgery.

- ✓ The HTCC reviewed and considered the pediatric bariatric surgery technology assessment report, information provided by the Administrator, and public and agency comments. Based on the technology assessment report, the cited studies, and information presented by the technology assessment center, committee members concluded that there were meaningful differences between the two primary surgical procedure types (RYGB and LAGB) and between individuals in the higher age bracket (18-21 years old) and those under 18 years old. Thus, where relevant to the question, certain findings were separated by the committee in these categories.
- ✓ Effectiveness: The committee found that there was sufficient scientific evidence, although weak because it was based on small, generally retrospective case studies, to draw conclusions about effectiveness. Three outcomes related to bariatric procedures were important: weight loss, reduction or elimination of medical co-morbidities, and improvement in psychological co-morbidities.
 - ❖ The committee was confident that the scientific evidence confirms that both LAGB and RYGB bariatric procedures were effective at inducing clinically significant weight loss.
 - ❖ The committee found that there was scientific evidence that confirms both LAGB and RYGB bariatric procedures improve at least some medical co-morbidity, but a majority was not confident in the evidence (e.g. while evidence is sufficient, further evidence could change results).
 - ❖ The committee found that the scientific evidence did not confirm that either LAGB or RYGB bariatric procedure improved psychological co-morbidity.

EFFECTIVENESS						
Compared to no treatment						
	Weight Loss		Co-Morbid		Psych	
	Y/N	Confid Y/N	Y/N	Confid Y/N	Y/N	Confid Y/N
Band	9/0	9/0	6/3	2/4	0/7 (2 abstain)	no vote
RYGB	9/0	9/0	6/3	1/5	0/9	no vote



EFFECTIVENESS						
Compared to an alternative						
	Weight Loss		Co-Morbid		Psych	
	Y/N	Confid Y/N	Y/N	Confid Y/N	Y/N	Confid Y/N
Band	4/5	2/2	3/6	2/1	0/8 (1 abstain)	no vote
RYGB	1/8	no vote	1/8	no vote	0/8 (1 abstain)	no vote

- ✓ Safety: The committee found that there was sufficient scientific evidence to make certain conclusions about whether LAGB and RYGB bariatric procedures are safe for patients under 21 years.

❖ *Patients under 18 years of age*

The committee found that there was insufficient scientific evidence to conclude that either LAGB or RYGB bariatric procedures are safe in patients under eighteen. Compelling concerns included the lack of evidence on the impact of performing the surgery on patients that have not yet reached full maturity, small but significant surgical complications, and concern over the ability of the patient to legally consent as well as adequately appreciate the long term impacts.

❖ *Patients 18 to 20 years of age*

The committee found that there was sufficient scientific evidence to conclude that the LAGB bariatric procedure is safe in patients aged eighteen to twenty, though a majority of committee members were not confident in the evidence. The committee found that there was insufficient scientific evidence to conclude that RYGB was safe in patients aged eighteen to twenty. Compelling concerns included the long term issues related to irreversibility, the more invasive surgical procedure, nutrition deficiency and malabsorption, and the increased and more serious procedural risks (reported post-operative death and serious surgical complications).

SAFETY					
Safety: 18 - 21 years of age			Safety: less than 18 years of age		
	Y/N	Confid Y/N		Y/N	Confid Y/N
Band	6/3	2/4	Band	0/8	no vote
RYGB	3/6	0/3	RYGB	0/8	no vote

- ✓ Cost: Committee members found that there were no independent cost analyses in any category. The cost to state agencies for bariatric surgery (including the facility and professional fees) was estimated to be \$16,000. This estimate does not include the pre-surgery multi-disciplinary care and surgery program or post surgical complications or outliers. Data was unavailable on other costs that could be saved through surgery, thus preventing committee members from estimating cost effectiveness.

COST							
Independent cost analysis less than 21 years old			If NO: will the use result in costs that are:				
	Y/N		Greater	Equivalent	Lower	Don't Know	
Band	No	Band	2	0	0	7	
RYGB	No	RYGB					



- ✓ **Benefit Evaluation:** A majority of committee members found that there was net benefit in morbidly obese patients aged 18-20 for the LAGB procedure based on the evidence regarding the technology’s safety and effectiveness and cost impact relative to currently available treatments. For the RYGB procedure, a majority of members found no net benefit either because there was insufficient evidence or because there was net harm. Considerations included the critical nature of morbid obesity and related medical co-morbid conditions; benefit of intervening after physical maturation but earlier in disease progression; the magnitude of potential benefit in significant weight loss and curing or preventing co-morbid conditions; sufficient, though low confidence, evidence; lack of effective alternative treatments; the relative safety profiles of the procedures; and the current agency selection criteria for adults used to mitigate certain risks. The committee will review this policy when new evidence is available that may inform a revision to this coverage determination.

BENEFIT EVALUATION					
Benefit for those 18 to 21 years of age					
	Net	Equivalent	Less	Net Harm	Don't Know
Band	6	0	0	0	3
RYGB	3	0	0	1	5
Coverage Determination for less than 18 years of age					
	Y/N	Don't Know			
Band	0/8	1			
RYGB	0/8	1			
If NO:	No. Evidence is insufficient to conclude that the health technology is safe, efficacious, and cost-effective.				
Coverage Determination for 18 to 21 years of age					
	Y/N	Coverage Determination			
Band	6/3	Yes: only when state agency guidelines are met			
RYGB	4/5	Evidence is insufficient to conclude that the health technology is safe, efficacious, and cost-effective.			

- **Outcome:** Committee’s coverage and reimbursement decision:
 - Pediatric Bariatric Surgery for patients under age 18 is **not a covered benefit** due to insufficient evidence to conclude that it is safe, efficacious, and cost-effective.
 - Pediatric Bariatric Surgery for patients aged 18 - 20 years is a **covered benefit** only under the criteria:
 - Patients aged 18 to 20 years old
 - Bariatric surgical procedure of Laparoscopic adjustable gastric banding only
 - Patients must meet and abide by all other agency bariatric surgery program criteria (e.g. body mass index, presence of co-morbid condition(s), pre-surgical weight loss, specified centers or practitioners)