



Health Technology Clinical Committee

Date: February 15, 2008

Time: 8:00 am – 5:00 pm

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

Teleconference Bridge: 360-923-2996 Access Code: 360-946-1464

D*R*A*F*T

HTCC MINUTES

Members Present: Brian Budenholzer; C. Craig Blackmore; Michael Myint; Carson Odegard; Daniel Abrahamson; Richard Phillips; Michelle Simon, Lydia Bartholomew, Louise Kaplan, and Jay Klarnet.

Members Absent: Michael Souter

HTCC Formal Action

1. **Call to Order:** Dr. Budenholzer, Chair, called the meeting to order at 8:00 a.m. Sufficient members were present to constitute a quorum.
2. **November 16, 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 November 16, 2007 minutes.
3. **Lumbar Fusion Findings and Decision:** Leah Hole-Curry briefed the committee on a discrepancy between the lumbar fusion published findings and decisions and the motion language used at the November 16th meeting. An updated findings and decisions document was prepared to reflect the motion language. Dr. Budenholzer referred members to the updated findings and decisions and called for discussion or objection, and received none.
 - *Outcome:* The committee unanimously approved the updated Lumbar fusion findings and decision document.
4. **Discography Determination:** The HTCC previously reviewed and considered the Discography technology assessment report, information provided by the Administrator, agency and public comments, and ECRI Institute's presentation. The topic was re-introduced; agency and public comments were given. 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.

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HTCC COMMITTEE COVERAGE DETERMINATION VOTE			
	Not covered	Covered Unconditionally	Covered Under Certain Conditions
Discography	10	0	0

- *Outcome:* The committee chair directed HTA staff to prepare a Findings and Decision document on Discography reflective of the majority vote for final approval at the next public meeting.

5. **Computed Tomographic Colonography Determination:** The HTCC reviewed and considered the CT Colonography technology assessment report, information provided by the Administrator, agency comments, ICER’s presentation, and 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.

HTCC COMMITTEE COVERAGE DETERMINATION VOTE			
	Not covered	Covered Unconditionally	Covered Under Certain Conditions
CT Colonography	9	0	1

- *Outcome:* The committee chair directed HTA staff to prepare a Findings and Decision document on CT Colonography reflective of the majority vote for final approval at the next public meeting.



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 February 15, 2008, to discuss:

- ✓ *Discography*: the evidence of the safety, efficacy and cost-effectiveness of Discography for patients with chronic uncomplicated low back pain.
- ✓ *CT Colonography*: the evidence of the safety, efficacy and cost-effectiveness of Computed Tomographic Colonography (CTC) for colorectal cancer screening.

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.
 - Key focus questions: Is it safe? Is it effective? Does it provide value?
- ✓ Program Progress: A stakeholder update is available listing current program activities
 - 3 topics from 2007 are in various implementation stages. For latest topic, lumbar fusion, agency discussion on implementation of the optional intensive program is underway;
 - 6 topics for 2008 are underway;
 - Program is updating website and conducting a quality review based on first year experience; and
 - Internal review, stakeholder comment, and HTCC retreat produced change suggestions that the chair has considered, some implemented, more suggestions will likely be promoted after discussion with all stakeholders

Dr. Brian Budenholzer, HTCC Chair, introduced the November minutes, which had been previously sent to committee members and posted to the HTA website, called for discussion, and motion to approve.

- ✓ No discussion, minutes were approved.
- ✓ Findings and Decision related to Lumbar Fusion, the November topic, were published but did not contain the exact motion language of the committee. An updated Findings and Decision was included in the package reflecting the exact motion language and was presented for approval. Document was approved without further discussion.

Agenda Item: Discography Topic Review

Dr. Dave Flum, HTA Clinical Consultant, presented an overview on Discography – the reason for topic selection and the technology assessment findings as the topic had been presented in depth at the November 2007 meeting.

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- ✓ Discography premise is to diagnose source of pain as from disc through an injection of contrast material to aid imaging of disc. Injection should provoke pain (look for corresponding facial / subjective response).
 - Provocative discography is a subjective test with a high false positive rate. Provocative discography is more likely to be (+) in the presence of psychosocial risk factors than anatomic findings.
- ✓ Concerned regarding using discography results to select or “confirm” a patient for fusion surgery. There is no clear case definition of presence/absence of degenerative disc disease. Association between disease presence, pain, and surgical benefit not established. Unclear that positive discogram patients undergoing surgery do better. Significant false positive rate.
- ✓ Diagnostic “gold standard” not established – generally, not recommended for uncomplicated cases or MRI or plain radiograph.
- ✓ High variation in nation in back surgery and in WA – up to a three fold difference based on geographic location
- ✓ Centers for Medicare and Medicaid Services (CMS): has no national Medicare coverage policy on spinal fusion or discography.
- ✓ Five entities published guidelines including discography: American Society of Interventional Pain Physicians (2007); Work loss Data Institute (2006); American Association of Neurological Surgeons (2005); Guyer and Ohnmeiss, Texas Back Institute (2003); and Washington State Department of Labor & Industries (2002).
 - Evidence relied upon for guideline not explicit / variable.
 - No guideline recommends discography as stand along pre-operative diagnostic test; MRI recommended as diagnostic test of choice.
 - Three guidelines indicate reserve for patients with equivocal or inconclusive MRI; two do not recommend use; one recommends against surgery if positive discogram but normal MRI.
- ✓ Key Questions for discography were on Reliability, Prediction value, and impact:
 - In patients being considered for lumbar fusion surgery, what is the reliability of discography?
 - In patients undergoing lumbar fusion surgery, do the results of pre-surgical discography predict the degree of pain reduction or improvement in functional status/quality of life after lumbar fusion surgery?
 - In patients being considered for lumbar fusion surgery, do patients who receive discography that influences the treatment choice have better treatment outcomes than patients who do not receive discography?
- ✓ No studies reported any of the following:
 - Reliability of discography result when different people perform the injection.
 - Reliability of discography on the same disc at different times.
 - Reliability of patients’ reports of pain provocation.



- ✓ Reliability subset – not enough data for conclusion. Three small studies exist on whether a given discogram is judged to have the same morphology grade:
 - By the same reader at different times (1 study, N=72).
 - By different readers (2 studies, N=72 and N=45).
- ✓ Prediction findings: 3 studies, all Low quality – not enough data for conclusion
 - Willems (2007): No difference in surgical outcomes between those with positive discography (+) and those with negative discography (-)
 - Gill (1992): Inconclusive findings
 - Colhoun (1988): Surgical outcomes were better among those with positive discography (+)
- ✓ Do patients receiving discography and fusion have better outcomes?
 - Only one study: N=32 who received discography and N=41 who did not
 - All patients received fusion; retrospective, non-concurrent, non-randomized, unblinded, poor matching at baseline; very low quality.

Agenda Item: Discography Topic – Agency Data

Dr. Gary Franklin, L&I Agency Medical Director, presented to the committee the agency utilization and outcomes for Discography.

- ✓ Agencies have a general coverage policy on diagnostics, currently includes discography without specific indications or limitations. L&I policy on fusion indicates that positive discogram is not sufficient alone as indicator for surgery.
 - Alternatives: the agencies cover discography alternatives, including: physical examination; MRI; and plain Radiography (X-ray).
- ✓ Washington State Agency outcome experience from a Labor and Industries 2006 study (Spine 31: 2715-23) of 1950 cases reported on scope, disability status, and safety profile for both post operative complications and Re-operations; included all surgeries from 1994-2001.
 - 63.9% disability at 2 years (214 cases or 11.3% total disability)
 - 22% re-operation rate; with instrumentation doubling re-operation risk
 - 11.8% (218 cases) serious postoperative complications
- ✓ Discography Agency Utilization (SFY 06):
 - L&I: 137 spending at \$305,000, average of \$2,230 per test
 - UMP: 4 with spending at \$8,800, average of \$2200 per test
 - DSHS: 7 with spending at \$9,800, average of \$1,400 per test

Agenda Item: Public Comments

- ✓ One individual provided public testimony for Discography: Dr. Aysel Atli, University of Washington.



Agenda Item: HTCC Discography Discussion and Vote

Brian Budenholzer, Committee Chair, led a discussion of the evidence related to the safety, efficacy, and cost effectiveness of Discography beginning with a discussion of what were key factors and/or health outcomes, and what evidence existed on those factors.

Discography:

Effectiveness: A majority of committee members found that current scientific evidence is lacking in key areas or is of insufficient quality to draw conclusions about discography's effectiveness. Outcomes on efficacy and effectiveness were the primary focus of the discography discussion. Three key efficacy factors included specificity; subjective findings related primarily to pain provocation; and reliability. The available evidence on specificity is of low quality and focuses on a secondary result of whether the same reader can later read the test in the same way; instead of the more substantive data on whether administering the test at different times produces the same results. The second issue is that the primary outcome relied upon in the test is the replication of normal pain. There is wide clinical debate on the ability to measure accurately, and the meaning of, the subjective pain response. The relevance is made more unclear by findings that there is no established clinical case definition for degenerative disc disease. The issue of false positives and reliability (percent agreement) are also a key concern raised by several studies, including the Carragee studies that demonstrated a high rate of positive discography findings in asymptomatic individuals. Patients may be subject to additional tests and risks of invasive therapies unnecessarily.

Safety: A majority of committee members found that the current scientific evidence is of insufficient quality to permit a conclusion on key health outcomes on the safety of Discography. Primary issues of concern here include the lack of a gold standard diagnosis and re-operation risk. The diagnostic test itself does include a small risk of infection and radiation common to any injection related test. The study results did not focus on safety concerns, and no other evidence on safety was presented. However, the committee did not have significant concern related to the performance of the test itself and acknowledged small risks as similar to other similar tests. The re-operation risk from surgeries performed as a result of the test is significant, especially where the test did not accurately identify the appropriate site. Appropriateness of surgery is a high concern that is unaddressed in the current trials. The substantial false positive rate of the test, discussed in efficacy, also contributes to this concern.

Cost: Half the committee members found that discography is less cost effective than the alternative tests, and half the committee members found that the evidence was insufficient to reach a conclusion on cost. The procedure fee itself and the need for referral for other tests were identified as key cost considerations. The cost of the procedure (agency average about \$2000 and \$8 million per year) is very high compared to alternatives and does not include any additional testing, treatments performed as a result of the test, or complications. Also, this is an additional test, not a replacement test. Discography is currently not used as a definitive test and it cannot replace other tests. Given high reliability concerns, more tests to confirm or refute findings can be required. No formal cost effectiveness evaluations and no long term costs were addressed.

Medicare Decision and Professional Guidelines: The committee found that Medicare does not have a national coverage decision on discography. No professional guideline recommends discography as a stand alone or pre-operative diagnostic test. MRI is recommended as the diagnostic test of choice. Several guidelines do not recommend its use at all, while several advocate its use in addition to other tests.

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Discography VOTES:

Is there sufficient evidence under some or all situations that the technology is:

	Inconclusive (no)	Equivalent (yes)	Less (yes)	More (yes)
Effective	10			
Safe	8	1	1	
Cost-effective	5		5	

HTCC Discography Coverage Decision

The overall question about the benefit of discography that the committee members focused on: do patients receiving discography have better treatment and health outcomes (surgical or otherwise). Key factors related to the impact that discography had on either the therapeutic decision or the surgical success. Three low quality studies addressed prediction of surgical success and outcomes were not favorable in two studies; no study addressed impact on therapeutic decisions. Current evidence does not demonstrate that the test produces reliable results, even though expert opinion evidence supported the use of discography to rule out surgery. Based on the evidence presented on safety, efficacy and cost-effectiveness, committee voted as follows.

HTCC COMMITTEE COVERAGE DETERMINATION			
	Not covered	Covered Unconditionally	Covered Under Certain Conditions
Discography	10	0	0

- Outcome: The committee chair directed HTA staff to prepare a Findings and Decision document on Discography reflective of the majority vote for final approval at the next public meeting.

Agenda Item: Computed Tomographic Colonography Topic Review

Dr. Dave Flum, HTA Clinical Consultant, introduced the CT Colonography topic overview.

CT Colonography

- ✓ CTC uses computer generated images to examine colon for lesions. Bowel cleansing / preparation is necessary, a rectal tube is inserted to insufflate colon with air / gas prior to radiographic imaging. No sedation required.
- ✓ Technology is not new, but this application is emerging. Pressure to screen asymptomatic patients at average risk of colon cancer. Scientifically (intellectually) and esthetically appealing.
- ✓ Benefits: Compliance is issue with CR screening – new test that is less invasive may increase screening rates; decrease in time; and decrease risk related to bowel perforation and anesthesia.
- ✓ Drawbacks: Test is additive (doesn't replace optical colonoscopy or others); test must be done more often and clinical uncertainty over findings (lesion size, disease progression, extra-colonic findings); cost is higher; no as sensitive / specific; and no uncertainty of radiation risk where used for routine, repeat screening.
- ✓ National Medicare Coverage: Medicare covers colorectal cancer screening tests, but not CTC.

Medicare Coverage Colon Cancer Screening (2004)

- Annual fecal occult blood tests (FOBTs);
 - Flexible Sigmoidoscopy over 4 years;
 - Screening colonoscopy for persons at average risk for colorectal cancer every 10 years, or for persons at high risk for colorectal cancer every 2 years;
 - Barium enema every 4 years as an alternative to flexible Sigmoidoscopy, or every 2 years as an alternative to colonoscopy for persons at high risk for colorectal cancer;
 - Other procedures the Secretary finds appropriate based on consultation with appropriate experts and organizations.
- ✓ Safety concerns: CTC is less invasive but same bowel prep and smaller perforation risk; reduces but does not eliminate risks of a 2nd procedure (true and false positives); radiation exposure, uncertain lifetime risk; benefit versus harm (identification of extra-colonic findings; unnecessary interventions); and potential of failed follow-up (compliance) or mid-sized lesions.
 - ✓ Effectiveness concerns: evidence of sensitivity, specificity, and reliability is worrisome; screening versus colonoscopy (screening, diagnostic, and therapeutic in one procedure) doesn't allow polypectomy (6 to 9 mm "polyp dilemma"); and no evidence of enhancing screening compliance rates.
 - ✓ Cost concerns: CTC has a higher testing frequency, higher cost / test; and added tests if suspicious lesions, equivocal results or poor study add to cost.

Agenda Item: Computed Tomographic Colonography Agency Data

Dr. Malcolm Dejnozka, UMP Medical Director, presented to the committee the agency utilization and outcomes for CT Colonography.



- ✓ CTC Agency Utilization (SFYs 2006 and 2007):
 - Conventional Colonoscopy (N=27,655) = \$20,231,011 (cost)
 - Sigmoidoscopy (N=1,548) = \$262,475 (cost)
 - Barium Enema (N=0) = \$0.00 (cost)
 - Virtual Colonoscopy (N=25) = \$22,824 (cost)

- ✓ The CTC technology report findings are consistent with other HTAs that generally CTC does not have proven benefit:
 - Hayes Inc. (2006) – potential but unproven benefit
 - BCBS TEC (2004) – CTC does not meet TEC criteria
 - ICSI (2004) – “unclear...sensitivity and specificity...limited available data” and “...not proven...superior to (OC)”
 - OHTAC (2003) – “...CTC cannot be proposed for population-based colorectal cancer screening.”
 - NZHTA (2007) – “...CTC is not currently recommended for generalized screening.”
 - ECRI (2005) – “...no published evidence of the effect of CT colonography on colorectal cancer incidence and mortality.”

- ✓ State Agencies Summary View:
 - CT Colonography screening diffusion in current “real world” settings not controlled as in ICER report – high variability: equipment, training, experience (quality) is problematic.
 - Safety issues not resolved – no evidence on radiation exposure; extra-colonic findings, polyp size and poor compliance present dilemmas.
 - Costs increase because not a replacement – costs for referral to optical; tests performed twice as often; and cost for extra-colonic findings and poor compliance undetermined.
 - No evidence of increase in screenings or improved health outcomes.
 - CT Colonography for CR cancer screening is promising but limited benefit and high cost.

Agenda Item: Technology Assessment Presentation

Steven D. Pearson, MD, MSc, FRCP from The Institute for Clinical and Economic Review (ICER) presented a summary of the technology assessment report.

- ✓ CTC is a technique in which a spiral CT scanner is used to acquire multiple simultaneous tomographic sections (“slices”) of the colon and rectum during one rotation of the x-ray source. Patients must take a cathartic bowel preparation regimen to empty the bowel the day before the procedure. At the time of the procedure, the patient is positioned on the CT scanner and a catheter is placed in the rectum to inflate the colon with air or carbon dioxide (“insufflation”). Two scans of the abdomen are then performed, one with the patient lying on their back, and one with the patient lying on their stomach. The patient does not require sedation, and the entire procedure usually takes less than 30 minutes for set-up and scanning.

- ✓ The accuracy of CTC has varied significantly in published studies over the years. In particular, the wide range of sensitivities (50% - 90%) for medium and large polyps has led many commentators and previous health technology assessment bodies to judge the evidence base for CTC inadequate to support broad adoption of CTC for population-based screening.

- ✓ Systematic Review Criteria: prospective diagnostic accuracy studies of CT colonography; Colonoscopy used as reference standard; Endoscopists unaware of index test results, CT readers unaware of reference test results; and study participants included: adults who have undergone CT colonography and colonoscopy with no active bowel disease (e.g., Crohn's disease, irritable bowel syndrome, etc). Populations were not restricted by risk status or demographic characteristics.
- ✓ Search results identified 149 articles (97 articles excluded); therefore, the total articles included in the review = 52 articles.
 - Criteria for "relevant" studies: multi-detector CT scanners with collimation < 5 mm; scan acquired within a single breath hold of ≤ 30 seconds; reference standard of combined CT colonoscopy and colonoscopy results (segmental unblended colonoscopy or second look colonoscopy); and observers had read at least 30 CT scans or receiving CTC training before study started.
- ✓ Study Quality: QUADAS tool – used to assess diagnostic accuracy studies; 14 items assessing internal validity. Five high quality studies – Ginnerup (2003); Iannaccone (2004 & 2005); Pickhardt (2003); and Taylor (2003). Four fair quality studies – Hoppe (2004); Johnson (2007); Rockey (2005); and Van Gelder (2004).
- ✓ Harms: Eleven investigators reported specifically on harms including adverse events and complications of treatment as well as level of radiation (page 34 on the ICER report); three investigators reported on events and on complications related to the cathartic colonic preparation (e.g., headache, nausea, and vomiting).
 - Nine cases of colonic perforation were reported in 17,067 CT colonographic examinations, a rate of 0.08% (Burling 2006). In a survey of 11 medical centers, Sosna (2006) reported seven cases in 11,870 examinations (0.06%) – it is important to point out that of the 16 instances of perforation, twelve occurred in patients with an existing colonic condition or disease (i.e., irritable bowel syndrome, inguinal hernia, diverticulosis, etc). By comparison, the rate of colonic perforation for optical colonoscopy is reported to be 0.13% (Burling 2006), significantly higher than the reported for CT colonography.
- ✓ Extracolonic Findings: A controversial feature of CTC is its concurrent ability to image and to detect abnormalities in extracolonic abdominal tissues. Particularly among otherwise healthy adults undergoing screening examinations, incidental lesions present a clinical and policy challenge because of the possible benefits of early detection of some significant lesions in the face of the overall likelihood that detection of such lesions will not prove clinically valuable but will instead engender unnecessary costs and risks that come with further investigation. Studies suggest that approximately 6% - 8% of asymptomatic adults will have an extracolonic finding with a recommendation for follow-up of some kind.
 - Benefits: 0.3% of patients had extracolonic cancers; other lesions: AAA, adrenal adenomas, cysts.
 - Harms: most lesions will not be clinically consequential; no data on complications of investigation; \$2.34 - \$34.33 per patient for follow-up.
- ✓ Radiation Exposure and Future Cancer Risk: potential adverse health effects associated with radiation exposure are an important factor to consider in the evaluation of CTC as a potential adjunct to population screening for colorectal cancer.



- ✓ Impact on Population screening: It is unclear whether the preference elicited among some patients for CTC would result in a larger number of unscreened individuals in a population becoming screened. No study to date has examined whether the availability of CT colonography results in increased numbers of individuals being screened within a population.
- ✓ Patient Acceptance: Four investigators examined patient-oriented outcomes, usually asking the patients after having experienced both procedures, which one – CT colonoscopy or optical colonoscopy – was preferred: of 1883 patients (in 4 included studies):
 - 48.7% preferred CTC
 - 41.3% preferred colonoscopy
 - 9.9% had no preference
- ✓ Cost-effectiveness assumptions: CTC with referral of all patients with > 6mm polyp every 5 years and price = \$522; optical colonoscopy price \$523.
 - Versus no screening: Cost to gain one year of life = \$1,500
 - Versus optical colonoscopy: Cost to gain one year of life = \$630,700
- ✓ Interpretation of Key Findings and Key Issues –
 - Key Findings: safe, well accepted; test characteristics compare favorably to alternative screening methods other than OC; comparable to OC for large polyps; slightly less sensitive for medium polyps but with q 5y strategy unlikely to miss significant lesions; highly effective and cost effective versus no screening; and comparative value versus optical colonoscopy depends on reimbursed price ration.
 - Key Issues: question of relevance of smaller polyps; system use of other screening methods; integration with colonoscopy; management of extra-colonic findings; advent of “non-cathartic” prep; and impact on population screening rates.

Agenda Item: Public Comments

- ✓ One individual provided public testimony for CT Colonography: Dr. J.G. Fletcher, Mayo Clinic.

Agenda Item: CT Colonography Technology Decision

Brian Budenholzer, Committee Chair, led a discussion of the evidence related to the safety, efficacy, and cost effectiveness of CT Colonography.

CT Colonography:

Effectiveness: Effectiveness was a key area of discussion for committee members. Factors that were important in the discussion included: overall reduction in CRC mortality; equipment and reader training variation; and specificity (true negative, false positive); sensitivity (small polyps, medium polyps, and large polyps). Over-arching discussion included the appropriate comparator and its evidence level. According to National Cancer institute, fecal occult blood testing is the only cancer screening that is proven by randomized control trials to reduce colorectal cancer deaths is completely non-invasive, and very inexpensive. Optical colonoscopy is often the comparator for CTC and is cited as a gold standard, but its relative effectiveness at the overall goal of reducing colorectal cancer is not proven by same quality studies.

Equipment variation and reader/provider training – the report appropriately identified a current level of equipment and training for study inclusion. However, the current community standard is not uniform- there is variation in both equipment and training levels and the ability to enforce requirements for a population screening test by state payers is limited – the result is likely lower

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equipment and reader training and commensurate results. Regarding specificity: the evidence report demonstrated clinically equivalent ability to identify individuals without cancer (relatively high true negative and low false positive, about equal to optical colonoscopy – see evidence table page 32). Regarding sensitivity (true positive and false negatives) the evidence was mixed and dependent on the polyp size – small polyps were disregarded by the group; medium polyps detection based on 3 moderate quality studies found approximately equal numbers of cancer to optical colonoscopy; and the large polyp group also found approximately equal numbers of cancer to optical colonoscopy-see evidence table page 55. However, one study's results were not pooled, and this lowered the sensitivity of virtual colonoscopy by 10% which was clinically relevant to some committee members. It was noted that sensitivity findings were based on centers and individuals having good training and equipment that may not be reflective of the providers that would service the state agency population. A majority of committee members found that the current scientific evidence is sufficient to demonstrate that in some or all cases, CTC is equivalent in efficacy.

Safety: Key health outcomes/factors important to the safety considerations for CTC were: invasiveness; bowel perforation; radiation exposure (accumulation); and extra-colonic findings. CTC is an invasive procedure due to bowel preparation (cleansing and air pressure through rectal tube to inflate colon), though different degree to optical colonoscopy. This is a key distinction for whether it involves some risk and related to whether the unpleasant aspect of screening is reduced enough to induce more individuals to get screened. Both CTC and OC have small risk of bowel perforation, but CTC rate is smaller as calculated by evidence report (.08 for CTC versus .13 for OC).

Radiation exposure is higher with CTC than OC, but this is expected because of test. Key issue is level of exposure and long term risk related to additive exposure for population screening every five years - long term effect is unknown and significant clinical debate on exposure risk – FDA estimate one new cancer per 2000 for standard dose abdominal CT. Evidence review comparisons: chest x-ray is .02; Low dose CTC is .5; abdominal CTC is 10-radiation worker exposure limit is 20 per year. Extra-colonic findings can be beneficial if clinically significant, but most findings are not and those produce additional unnecessary testing and strain for patients. Evidence report indicates between 6 and 8% of tests in studies had extra-colonic finding with 0.3% of patients found to have extra-colonic cancers. Committee members found that both tests had safety related trade-offs, though likely low risk; evidence supported a finding that CTC was either equivalent or more safe than optical colonoscopy.

Cost: Due to the close findings related to safety and effectiveness, cost outcomes were important, including; the cost of the procedure; referral rate to additional procedures (optical colonoscopy); and extra-colonic findings. The technology report cost findings included: not currently priced (national/Medicare), most private payers do not reimburse, estimate cost \$522 for CTC and \$523 OC. Technology report cost conclusions included: break even at half price of OC; low value if same or higher price than OC; higher value if one-third the cost of OC. Agency utilization data indicated that FoBT: \$7, OC: \$723; CTC\$912. Current screening costs with CTC annually are 10 million; and to screen the same population with CTC would increase costs to between 26 to 30 million.

Regarding additional tests required upon a CTC finding: the technology report rate of referral for follow up in studies was 14% and the referral rate for HCA paid CTC's was 40%. Limited information on cost of extra-colonic findings was presented in the tech report estimated at about \$2-\$34 per screening. Cost became a key element of discussion - for some committee members, if costs were lowered to one-third of OC, then this essentially equivalent option would become beneficial. Limited current reimbursement experience is that the cost is higher than CTC. Committee members found that current



evidence either indicated that there CTC was less cost effective than alternatives or that there was insufficient evidence to make a conclusion about cost-effectiveness.

CTC VOTES

Is there sufficient evidence under some or all situations that the technology is:

	Inconclusive (no)	Equivalent (yes)	Less (yes)	More (yes)
Effective	1	7	1	1
Safe		6		4
Cost-effective	6		4	

HTCC CT Colonography Coverage Decision

A key overall benefit question committee members focused on: would adding CTC to the currently available methods to screen for colorectal cancer reduce cancer deaths. Factors considered related to the impact of CTC on cancer deaths, in addition to the safety and efficacy data include whether there was demonstrated patient preference, access to alternatives, and an impact on screening rates. Some evidence (expert opinion) supports the concept that current providers cannot accommodate optical screening if all patients were screened, therefore arguing for additional methods. Anecdotal and agency utilization do not demonstrate a provider access issue that creates a barrier for individuals to receive CRC screening. Limited patient preference data was gathered from the studies that showed approximately equal, though slightly greater preference for CTC (48%) compared to OC(41%) with 10% having no preference. No study evaluated key concern of impact of CTC on overall population screening rates. Based on the evidence presented on safety, efficacy and cost-effectiveness, committee voted as follows:

HTCC COMMITTEE COVERAGE DETERMINATION VOTE			
	Not covered	Covered Unconditionally	Covered Under Certain Conditions
CT Colonography	9	0	1

- *Outcome:* The committee chair directed HTA staff to prepare a Findings and Decision document on CT Colonography reflective of the majority vote for final approval at the next public meeting.

Health Technology Clinical Committee**Findings and Coverage Decision****Topic: Computed Tomographic Colonography (CTC)****Meeting Date: February 15, 2008****Final Adoption:*****D*R*A*F*T****Number and Coverage Topic**

20080215B – Computed Tomographic Colonography (CTC)

HTCC Coverage Determination

Computed Tomographic Colonography (CTC) for routine colorectal cancer screening is **not a covered benefit**. This decision does not apply to use of CTC for other diagnostic purposes.

HTCC Reimbursement Determination**❖ Limitations of Coverage**

Not Applicable

❖ Non-Covered Indicators

Routine Colorectal Cancer screening

❖ Agency Contact Information

Agency	Contact Phone Number
Labor and Industries	1-800-547-8367
Uniform Medical Plan	1-800-762-6004
Health and Recovery Services Administration	1-800-562-3022

Health Technology Background

Colon cancer is the nation's second leading cause of cancer deaths, and an estimated 52,000 people will die from it this year. Screening can save lives by finding growths before they turn cancerous, yet only about one-half the population gets recommended screening. Current colorectal cancer screening tests include: Fecal Occult Blood testing, Barium enema, Sigmoidoscopy, and conventional or optical colonoscopy (OC).

CTC has been proposed as a less invasive alternative to conventional colonoscopy to screen for colorectal cancer, with the potential to induce more individuals to get screened. Colonoscopies, considered a gold standard test, are recommended every 10 years for everyone over 50 and more frequently after polyps are found or for high risk individuals. Optical colonoscopy involves taking laxatives to cleanse the bowel and sedation for the procedure. A tube is inserted in the rectum and snaked through the large intestines by a gastroenterologist. Generally, any polyps that are spotted, regardless of size, are taken out in the process. CTC involves taking laxatives to cleanse the bowel and inflating the

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colon with air or gas using a small tube inserted in the rectum. A CT scanner is used to take a series of X-rays of the colon and a computer to create a 3-D view. A radiologist then checks the images for suspicious polyps. If any polyps need to be removed, the patient must then have a regular colonoscopy.

Benefits are thought to include an increase in patient compliance for screening recommendations and less risk of bowel perforation than conventional colonoscopy. Harms may include bowel perforation and radiation exposure, accuracy of the imaging tests leading to false results, the need for an additional procedure, conventional colonoscopy, if the CTC finds polyps that need removed and the inability of the screening to view polyps that are less than 5mm.

Summary of Committee Findings

The HTCC reviewed and considered the CT Colonography technology assessment report, information provided by the Administrator, and public and agency comments. A key overall benefit question committee members focused on: would adding CTC to the currently available methods to screen for colorectal cancer reduce cancer deaths. Factors considered related to the impact of CTC on cancer deaths, in addition to the safety and efficacy data include whether there was demonstrated patient preference, access to alternatives, and an impact on screening rates. Some evidence (expert opinion) supports the concept that current providers cannot accommodate optical screening if all patients were screened, therefore arguing for additional methods. Anecdotal and agency utilization do not demonstrate a provider access issue that creates a barrier for individuals to receive CRC screening. Limited patient preference data was gathered from the studies that showed approximately equal, though slightly greater preference for CTC (48%) compared to OC (41%) with 10% having no preference. No study evaluated the key concern of the impact of CTC on overall population screening rates. Based on the evidence presented on safety, efficacy and cost-effectiveness, committee voted for non-coverage.

Effectiveness: Effectiveness was a key area of discussion for committee members. Factors that were important in the discussion included: overall reduction in CRC mortality; equipment and reader training variation; and specificity (true negative, false positive); sensitivity (small polyps, medium polyps, and large polyps). Over-arching discussion included the appropriate comparator and its evidence level. According to National Cancer institute, fecal occult blood testing is the only cancer screening that is proven by randomized control trials to reduce colorectal cancer deaths is completely non-invasive, and very inexpensive. Optical colonoscopy is often the comparator for CTC and is cited as a gold standard, but its relative effectiveness at the overall goal of reducing colorectal cancer is not proven by same quality studies.

Equipment variation and reader/provider training – the report appropriately identified a current level of equipment and training for study inclusion. However, the current community standard is not uniform- there is variation in both equipment and training levels and the ability to enforce requirements for a population screening test by state payers is limited – the result is likely lower equipment and reader training and commensurate results. Regarding specificity: the evidence report demonstrated clinically equivalent ability to identify individuals without cancer (relatively high true negative and low false positive, about equal to optical colonoscopy – see evidence table page 32). Regarding sensitivity (true positive and false negatives) the evidence was mixed and dependent on the polyp size – small polyps were disregarded by the group; medium polyps detection based on 3 moderate quality studies found approximately equal numbers of cancer to optical colonoscopy; and the large polyp

group also found approximately equal numbers of cancer to optical colonoscopy-see evidence table page 55. However, one study's results were not pooled, and this lowered the sensitivity of virtual colonoscopy by 10% which was clinically relevant to some committee members. It was noted that sensitivity findings were based on centers and individuals having good training and equipment that may not be reflective of the providers that would service the state agency population. A majority of committee members found that the current scientific evidence is sufficient to demonstrate that in some or all cases, CTC is equivalent in efficacy.

Safety: Key health outcomes important to the safety considerations for CTC were: invasiveness; bowel perforation; radiation exposure (accumulation); and extra-colonic findings. CTC is an invasive procedure due to bowel preparation (cleansing and air pressure through rectal tube to inflate colon), though different degree to optical colonoscopy. This is a key distinction for whether it involves some risk and related to whether the unpleasant aspect of screening is reduced enough to induce more individuals to get screened. Both CTC and OC have small risk of bowel perforation, but CTC rate is smaller as calculated by evidence report (.08 for CTC versus .13 for OC).

Radiation exposure is higher with CTC than OC, but this is expected because of test. Key issue is level of exposure and long term risk related to additive exposure for population screening every five years - long term effect is unknown and significant clinical debate on exposure risk – FDA estimate one new cancer per 2000 for standard dose abdominal CT. Evidence review comparisons: chest x-ray is .02; Low dose CTC is .5; abdominal CTC is 10- radiation worker exposure limit is 20 per year. Extra-colonic findings can be beneficial if clinically significant, but most findings are not and those produce additional unnecessary testing and strain for patients. Evidence report indicates between 6 and 8% of tests in studies had extra-colonic finding with 0.3% of patients found to have extra-colonic cancers. Committee members found that both tests had safety related trade-offs, though likely low risk; evidence supported a finding that CTC was either equivalent or more safe than optical colonoscopy.

Cost: Due to the close findings related to safety and effectiveness, cost outcomes were important, including; the cost of the procedure; referral rate to additional procedures (optical colonoscopy); and extra-colonic findings. The technology report cost findings included: not currently priced (national/Medicare), most private payers do not reimburse, estimate cost \$522 for CTC and \$523 OC. Technology report cost conclusions included: break even at half price of OC; low value if same or higher price than OC; higher value if one-third the cost of OC. Agency utilization data indicated that FoBT: \$7, OC: \$723; CTC\$912. Current screening costs with CTC annually are 10 million; and to screen the same population with CTC would increase costs to between 26 to 30 million.

Regarding additional tests required upon a CTC finding: the technology report rate of referral for follow up in studies was 14% and the referral rate for HCA paid CTC's was 40%. Limited information on cost of extra-colonic findings was presented in the tech report estimated at about \$2-\$34 per screening. Cost became a key element of discussion - for some committee members, if costs were lowered to one-third of OC, then this essentially equivalent option would become beneficial. Limited current reimbursement experience is that the cost is higher than CTC. Committee members found that current evidence either indicated that there CTC was less cost effective than alternatives or that there was insufficient evidence to make a conclusion about cost-effectiveness.

Committee Authority

The Washington State [Health Technology Clinical Committee \(HTCC\)](#), an independent committee of 11 health practitioners, determines how selected health technologies are covered by several state agencies. RCW 70.14.080-140. These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases their decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Evidence includes a report concerning the technology provided by a company specializing in objective reviews of pertinent scientific literature; information submitted by the affected state agencies; and public comment. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be reviewed at the determination of the HCA Administrator.

DRAFT

Health Technology Clinical Committee**Findings and Coverage Decision****Topic: Computed Tomographic Colonography (CTC)****Meeting Date: February 15, 2008****Final Adoption:*****D*R*A*F*T****Number and Coverage Topic**

20080215B – Computed Tomographic Colonography (CTC)

HTCC Coverage Determination

Computed Tomographic Colonography (CTC) for routine colorectal cancer screening is **not a covered benefit**. This decision does not apply to use of CTC for other diagnostic purposes.

HTCC Reimbursement Determination**❖ Limitations of Coverage**

Not Applicable

❖ Non-Covered Indicators

Routine Colorectal Cancer screening

❖ Agency Contact Information

Agency	Contact Phone Number
Labor and Industries	1-800-547-8367
Uniform Medical Plan	1-800-762-6004
Health and Recovery Services Administration	1-800-562-3022

Health Technology Background

Colon cancer is the nation's second leading cause of cancer deaths, and an estimated 52,000 people will die from it this year. Screening can save lives by finding growths before they turn cancerous, yet only about one-half the population gets recommended screening. Current colorectal cancer screening tests include: Fecal Occult Blood testing, Barium enema, Sigmoidoscopy, and conventional or optical colonoscopy (OC).

CTC has been proposed as a less invasive alternative to conventional colonoscopy to screen for colorectal cancer, with the potential to induce more individuals to get screened. Colonoscopies, considered a gold standard test, are recommended every 10 years for everyone over 50 and more frequently after polyps are found or for high risk individuals. Optical colonoscopy involves taking laxatives to cleanse the bowel and sedation for the procedure. A tube is inserted in the rectum and snaked through the large intestines by a gastroenterologist. Generally, any polyps that are spotted, regardless of size, are taken out in the process. CTC involves taking laxatives to cleanse the bowel and inflating the

Draft version not officially adopted yet

colon with air or gas using a small tube inserted in the rectum. A CT scanner is used to take a series of X-rays of the colon and a computer to create a 3-D view. A radiologist then checks the images for suspicious polyps. If any polyps need to be removed, the patient must then have a regular colonoscopy.

Benefits are thought to include an increase in patient compliance for screening recommendations and less risk of bowel perforation than conventional colonoscopy. Harms may include bowel perforation and radiation exposure, accuracy of the imaging tests leading to false results, the need for an additional procedure, conventional colonoscopy, if the CTC finds polyps that need removed and the inability of the screening to view polyps that are less than 5mm.

Summary of Committee Findings

The HTCC reviewed and considered the CT Colonography technology assessment report, information provided by the Administrator, and public and agency comments. A key overall benefit question committee members focused on: would adding CTC to the currently available methods to screen for colorectal cancer reduce cancer deaths. Factors considered related to the impact of CTC on cancer deaths, in addition to the safety and efficacy data include whether there was demonstrated patient preference, access to alternatives, and an impact on screening rates. Some evidence (expert opinion) supports the concept that current providers cannot accommodate optical screening if all patients were screened, therefore arguing for additional methods. Anecdotal and agency utilization do not demonstrate a provider access issue that creates a barrier for individuals to receive CRC screening. Limited patient preference data was gathered from the studies that showed approximately equal, though slightly greater preference for CTC (48%) compared to OC (41%) with 10% having no preference. No study evaluated the key concern of the impact of CTC on overall population screening rates. Based on the evidence presented on safety, efficacy and cost-effectiveness, committee voted for non-coverage.

Effectiveness: Effectiveness was a key area of discussion for committee members. Factors that were important in the discussion included: overall reduction in CRC mortality; equipment and reader training variation; and specificity (true negative, false positive); sensitivity (small polyps, medium polyps, and large polyps). Over-arching discussion included the appropriate comparator and its evidence level. According to National Cancer institute, fecal occult blood testing is the only cancer screening that is proven by randomized control trials to reduce colorectal cancer deaths is completely non-invasive, and very inexpensive. Optical colonoscopy is often the comparator for CTC and is cited as a gold standard, but its relative effectiveness at the overall goal of reducing colorectal cancer is not proven by same quality studies.

Equipment variation and reader/provider training – the report appropriately identified a current level of equipment and training for study inclusion. However, the current community standard is not uniform- there is variation in both equipment and training levels and the ability to enforce requirements for a population screening test by state payers is limited – the result is likely lower equipment and reader training and commensurate results. Regarding specificity: the evidence report demonstrated clinically equivalent ability to identify individuals without cancer (relatively high true negative and low false positive, about equal to optical colonoscopy – see evidence table page 32). Regarding sensitivity (true positive and false negatives) the evidence was mixed and dependent on the polyp size – small polyps were disregarded by the group; medium polyps detection based on 3 moderate quality studies found approximately equal numbers of cancer to optical colonoscopy; and the large polyp

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Safety: Key health outcomes important to the safety considerations for CTC were: invasiveness; bowel perforation; radiation exposure (accumulation); and extra-colonic findings. CTC is an invasive procedure due to bowel preparation (cleansing and air pressure through rectal tube to inflate colon), though different degree to optical colonoscopy. This is a key distinction for whether it involves some risk and related to whether the unpleasant aspect of screening is reduced enough to induce more individuals to get screened. Both CTC and OC have small risk of bowel perforation, but CTC rate is smaller as calculated by evidence report (.08 for CTC versus .13 for OC).

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Committee Authority

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Health Technology Clinical Committee**Findings and Coverage Decision****Date: February 15, 2008****Topic: Discography****Final Adoption:*****D*R*A*F*T*****Number and Coverage Topic**

20080215B – Discography

HTCC Coverage Determination

Discography for patients with chronic low back pain and lumbar degenerative disc disease is **not a covered benefit**. This decision does not apply to patients with the following conditions:

- Radiculopathy
- Functional neurologic deficits (motor weakness or EMG findings of radiculopathy)
- Spondylolisthesis (>Grade 1)
- Isthmic spondylolysis
- Primary neurogenic claudication associated with stenosis
- Fracture, tumor, infection, inflammatory disease
- Degenerative disease associated with significant deformity

HTCC Reimbursement Determination

- ❖ **Limitations of Coverage**
Not applicable.
- ❖ **Non-Covered Indicators**
Not applicable.
- ❖ **Agency Contact Information**

Agency	Contact Phone Number
Labor and Industries	1-800-547-8367
Uniform Medical Plan	1-800-762-6004
Health and Recovery Services Administration	1-800-562-3022

Health Technology Background

Low back pain is the most common cause of disability and loss of productivity in patients under age 45. Disabling, chronic low back pain impacts 1.2 million patients in the United States. One difficulty in treating chronic low back pain is the lack of a precise and agreed clinical definition or diagnosis for the cause of certain back pain.

Some clinicians believe that the source of pain is the intervertebral disc, and if appropriately identified, treatments to reduce the disc-related pain will be effective. Discography's premise is to diagnose the source of pain as coming from the disc itself (i.e., a diagnosis of discogenic pain) through two findings: a CT image aided by injection of contrast material to identify disc morphology or shape, and the provocation of pain by the injection that reproduces the pain typically felt by the patient.

Controversy in using the test exists because the clinical importance of these two test results is unknown and there is significant evidence of false positive test results. Some clinicians believe that the high false positive rate more accurately identifies patients with psychological co-morbidities rather than discogenic abnormalities.

The potential impact on the health system is unknown. Potential benefits include an accurate identification of individuals with degenerative disc disease and discogenic pain, which can potentially lead to effective interventions and a reduction in back pain and disability. Where other clinical findings are lacking, discography results are sometimes used to justify the need for surgical and other interventions. Theoretically, if the test accurately identifies a condition that will respond to surgical intervention, it will lead to better outcomes. The potential burden to the health system is the patient discomfort and relatively high cost of the diagnostic test, and the cost of unnecessary treatments and burden to the patient associated with a misdiagnosis (either due to false positives or due to the underlying clinical relevance not being accurate).

Summary of Committee Findings

The HTCC reviewed and considered the discography technology assessment report, information provided by the Administrator, and public and agency comments. The overall question about the benefit of discography that the committee members focused on was whether or not do patients receiving discography have better treatment and health outcomes (surgical or otherwise). Key factors were related to the impact that discography had on either the therapeutic decision or the surgical success. Three low quality studies that addressed prediction of surgical success and outcomes were found to be not favorable in two studies; no study addressed impact on therapeutic decisions. Current evidence does not demonstrate that the test produces reliable results, even though expert opinion evidence supported the use of discography to rule out surgery. Based on the evidence presented on safety, efficacy and cost-effectiveness, the committee voted for non-coverage.

Effectiveness: A majority of committee members found that current scientific evidence is lacking in key areas or is of insufficient quality to draw conclusions about discography's effectiveness. Outcomes on efficacy and effectiveness were the primary focus of the discography discussion. Three key efficacy factors included specificity; subjective findings related primarily to pain provocation; and reliability. The available evidence on specificity is of low quality and focuses on a secondary result of whether the same reader can later read the test in the same way; instead of the more substantive data on whether administering the test at different times produces the same results. The second issue is that the primary outcome relied upon in the test is the replication of normal pain. There is wide clinical debate on the ability to measure accurately, and the meaning of, the subjective pain response. The relevance is made more unclear by findings that there is no established clinical case definition for degenerative disc disease other than radiographic and other imaging descriptions. The issue of false positives and reliability (percent agreement) are also a key concern raised by several studies, including the Carragee studies that demonstrated a high rate of positive

discography findings in asymptomatic individuals. Patients may be subject to additional tests and risks of invasive therapies unnecessarily.

Safety: A majority of committee members found that the current scientific evidence is of insufficient quality to permit a conclusion on key health outcomes on the safety of Discography. Primary issues of concern here include the lack of a gold standard diagnosis and re-operation risk. The diagnostic test itself does include a small risk of infection and radiation common to any injection related test. The study results did not focus on safety concerns, and no other evidence on safety was presented. However, the committee did not have significant concern related to the performance of the test itself and acknowledged small risks as similar to other similar tests. The re-operation risk from surgeries performed as a result of the test is significant, especially where the test did not accurately identify the appropriate site. Appropriateness of surgery is a high concern that is unaddressed in the current trials. The substantial false positive rate of the test, discussed in efficacy, also contributes to this concern.

Cost: Half the committee members found that discography is less cost effective than the alternative tests, and half the committee members found that the evidence was insufficient to reach a conclusion on cost. The procedure fee itself and the need for referral for other tests were identified as key cost considerations. The cost of the procedure (agency average about \$2000 and \$8 million per year) is very high compared to alternatives and does not include any additional testing, treatments performed as a result of the test, or complications. Also, this is an additional test, not a replacement test. Discography is currently not used as a definitive test and it cannot replace other tests. Given high reliability concerns, more tests to confirm or refute findings can be required. No formal cost effectiveness evaluations and no long term costs were addressed.

The committee found that Medicare does not have a national coverage decision on discography. No professional guideline recommends discography as a stand alone or pre-operative diagnostic test. MRI is recommended as the diagnostic test of choice. Several guidelines do not recommend its use at all, while several advocate its use in addition to other tests.

Committee Authority

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