Health Services Advisory Council

Evidence Summaries and Legislative Reports

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Screening Ultrasound in Uncomplicated Pregnancy

Health Services Advisory Council

Evidence Summary

January 10, 2008

Minnesota Department of **Human Services**

Background/Context

Ultrasound is the most common imaging modality in pregnancy because it is non-invasive, does not use ionizing radiation, and has a relatively low unit cost. The technology visualizes the reflection of ultrasonic waves directed into tissue of varying density, and the reflection of these sound waves to a transducer is translated as an image. Ultrasound of the fetus allows clinicians to estimate gestational age and detect multiple pregnancies, as well as to detect other conditions that may affect maternal or perinatal morbidity and mortality such as genetic and developmental abnormalities, fetal malformations, intrauterine growth retardation, fetal presentation, and low-lying placenta. The optimal timing of ultrasound depends largely on the clinical objective: dating of pregnancy is best achieved during the first trimester, fetal abnormalities are optimally detected after 22 weeks, and assessments of growth and fetal presentation are detected in the third trimester.[1] Screening ultrasound is not universal in the U.S., but its use is increasing. The Centers for Disease Control and Prevention (CDC) reports that the percentage of women having at least one ultrasound examination during pregnancy nationwide increased from 48% in 1989 to 67% in 2001[2] and experts estimate current rates to be in the range of 70-80%.[3] In addition to the clinical objectives listed above, reasons cited for screening ultrasound include the family's desire to know the fetal sex, to obtain a picture of the fetus, and to encourage parental bonding.[4]

In Minnesota, roughly 35% of all births statewide are financed by Medicaid, which is below the national average of 41.3%.[5] In the Minnesota Health Care Programs (MHCP) fee-for-service population, expenditures for screening ultrasound topped $2.68 million in calendar year 2006, with enrollment-adjusted (PMPM) spending on these procedures increasing 75% from 2002 through 2006. Assessments of the efficacy of screening ultrasound in uncomplicated pregnancy must evaluate the tests' relationship to maternal and perinatal health outcomes. Additionally, the potential risks associated with false positive and false negative results should be considered. Screening ultrasound appears to be approaching standard practice, and it is crucial to examine the clinical evidence to evaluate its role in uncomplicated pregnancy.

Summary of the Evidence

The evidence reviewed for this summary includes one meta-analysis, three systematic reviews/technology assessments, and five sets of clinical practice guidelines based upon the same methodologies. The materials examine an overlapping body of literature, composed chiefly of 12 randomized trials and a number of non-randomized trials performed in the 1980s and 1990s comparing screening ultrasound to clinically indicated ultrasound.[6] The documents reviewed acknowledge that the appropriate role of ultrasound screening in uncomplicated pregnancy is controversial, and the guidelines come to varying conclusions based upon essentially the same evidence. The conclusions of each source document are summarized below.

A meta-analysis and three technology assessments based on systematic reviews were evaluated, and the scope of these documents ranged from specific indications for screening to the overall management of prolonged pregnancy:

- A 2003 meta-analysis by the ECRI Institute looked at "Ultrasound Screening of Normal-Risk Women for Prevention of Postterm Pregnancy". The scope of this document is limited to the use of ultrasound to determine gestational age. The ECRI Institute concluded that (based on 10 trials representing approximately 50,000 women) the routine use of ultrasound in normal-risk populations was associated with a modest reduction in perinatal mortality, although the statistical significance was marginal. The study also concluded that for this population ultrasound may reduce the need for induction of labor, but does not affect cesarean section rates.

- A Cochrane Review conducted in 1998 evaluated ultrasound for fetal assessment in early pregnancy. The scope of this review is broader than the ECRI Institute study in that it covers additional uses of ultrasound such as the diagnosis of fetal malformation and the detection of multiple pregnancies, but is limited in that it considers only ultrasound prior to 24 weeks. The author concluded that routine ultrasound in early pregnancy appeared to have diagnostic efficacy in assessing gestational age, detecting multiple pregnancies, and detecting clinically unsuspected fetal malformation at a time when termination of pregnancy is possible. However, the relationship with other substantive outcomes was not established.

- In 2002, the Institute for Clinical Systems Improvement (ICSI) updated its technology assessment on prenatal ultrasound as a screening test. The ICSI committee concluded that although ultrasounds are safe, the risks associated with false results (positive or negative) should be considered. The paper also concludes that routine ultrasound in early pregnancy (before 24 weeks) has not been shown to reduce perinatal mortality, and that ultrasound in late pregnancy (after 24 weeks) has not been shown to reduce either mortality or morbidity. However, the committee further concluded that routine ultrasound in early pregnancy "may be of benefit for gestational age assessment, inductions of labor for post-term pregnancies, detection of multiple pregnancies…, and earlier detection of clinically unsuspected fetal malformation."[7]

- The Agency for Healthcare Research and Quality (AHRQ)'s Duke Evidence-Based Practice Center conducted a systematic review in 2002 on the management of prolonged pregnancy, which addressed ultrasound tangentially. The paper concluded that ultrasound is efficacious in detecting birthweight greater than 4,000 grams in prolonged pregnancy, but that there is insufficient evidence regarding the link between diagnosing birthweights greater than 4,000 grams and outcomes.

Two sets of clinical practice guidelines were reviewed which dealt exclusively with the use of ultrasound in pregnancy:

- In 1998 the U.S. Preventive Services Task Force (USPSTF) published a guideline on the use of screening ultrasound in pregnancy. Citing the fact that "neither early, late, nor serial ultrasound in normal pregnancy has been proven to improve perinatal morbidity or mortality",[8] the USPSTF recommended against routine ultrasound in the third trimester. Additionally, they concluded that there was insufficient evidence to make a recommendation regarding a single routine mid-trimester ultrasound in low-risk pregnancies. These recommendations applied only to routine screening ultrasounds, and not to diagnostic ultrasound for specific clinical indications.

- A 2004 guideline from The Finnish Medical Society (Duodecim), focused on ultrasound during pregnancy. The guideline makes recommendations about the appropriate dates for various ultrasound indications (20 weeks for determining gestational age, 16-20 weeks for scanning fetal structures, and unnecessary in late pregnancy for low-risk pregnancies), but does not make explicit conclusions about screening ultrasound in uncomplicated pregnancy.

An additional three sets of guidelines evaluated ultrasound as one component of the overall management of uncomplicated pregnancy:

- ICSI's guideline on routine prenatal care was updated in 2007. The ICSI work group acknowledged the controversy that exists due to the near-universality of ultrasound in prenatal care despite the fact that "there is no scientific data available to support improved fetal outcome as a result of routine ultrasound."[9] The ICSI document recommends performing an ultrasound at 16-18 weeks as a compromise, allowing for a single ultrasound to evaluate gestational age and anatomy, as well as to evaluate genetic abnormalities at a time when termination can be considered.

- In 2002 the Veterans Health Administration (VA) and the Department of Defense (DoD) published a practice guideline for the management of uncomplicated pregnancy. The DoD/Va recommends routine ultrasound exams for women in low-risk pregnancy, conducted at 16-20 weeks, preceded by counseling and education and conducted and interpreted by appropriately trained providers. However, the guideline ranks the evidence on which the ultrasound recommendation is based as III (its lowest score), meaning the conclusion is drawn from expert opinion, clinical experience, and case reports rather than robustly-designed studies that evaluate outcomes.

- The UK National Collaborating Center for Women's and Children's Health (NCC-WCH) published a guideline in 2003 on routine care for the healthy woman pregnant woman, which addressed screening ultrasound. The UK guideline recommends early ultrasound for gestational age assessment and assessment of multiple pregnancies, ideally between 10 and 13 weeks, as well as at 18-20 weeks to detect structural anomalies.

Policy Options

The evidence for routine screening ultrasound in uncomplicated pregnancy is incomplete: ultrasound has diagnostic efficacy, yet the link between screening ultrasound and improved outcomes is weak. There is broad support in the evidence for diagnostic ultrasound in the presence of specific medical indications (such as bleeding or suspected congenital anomaly based on risk factors),[10] which must remain conceptually separate from its use as a standard screening tool in uncomplicated pregnancies. Despite the uncertain state of the evidence, the use of ultrasound appears to be increasing. Patient expectations and the prevailing standard of practice must be weighed against issues of cost and efficacy in evaluating coverage policy in this area. Ultrasound is currently unmanaged in the MHCP fee-for-service programs, and must be coded and billed independently from global billing methods for obstetric care.[11] From this information, a number of policy options emerge for the MHCP fee-for-service population:

- DHS could continue to cover all ultrasound for pregnancy.

- Coverage policy could allow a single screening ultrasound in all women, ideally conducted at 16-20 weeks (per the ICSI and DoD/VA guidelines). Additional ultrasound exams would require prior authorization, requiring documentation of medical necessity. Since ultrasound in pregnancy is such a high-volume service (performed on nearly 15,000 unique beneficiaries in 2006), this would preclude DHS from having to conduct authorizations on each and every ultrasound and would focus administrative resources on the exams that fall outside of the ICSI guideline.

- Payment for ultrasound could be bundled into a global fee for obstetrical services, as opposed to DHS' current policy of separate billing for ultrasound. This would leave decisions regarding ultrasound up to provider and patient, while shifting some of the financial risk for the procedures to the provider.

- Coverage policy could be restricted to allow ultrasound only for specific clinical indications. This would effectively remove coverage of ultrasound as a screening tool, and would require DHS to conduct prior authorization on every fetal ultrasound conducted in fee-for-service.

Proposed Codes

CPT

76801 - Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, first trimester (< 14 weeks 0 days), transabdominal approach; single or first gestation

76802 - Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, first trimester (< 14 weeks 0 days), transabdominal approach; each additional gestation (List separately in addition to code for primary procedure)

76805 - Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, after first trimester (> or = 14 weeks 0 days), transabdominal approach; single or first gestation

76810 - Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, after first trimester (> or = 14 weeks 0 days), transabdominal approach; each additional gestation (List separately in addition to code for primary procedure

76817 - Ultrasound, pregnant uterus, real time with image documentation, transvaginal

References

[1] Oregon Health & Science University (OHSU) Center for Evidence-Based Policy. *Screening Ultrasound in Uncomplicated Pregnancy*. Portland, OR. (2006).

[2] ECRI Institute. Windows on Medical Technology: Ultrasound Screening of Normal-Risk Women for Prevention of Postterm Pregnancy. Plymouth Meeting, PA. (2003).

[3] OHSU.

[4] ECRI Institute.

[5] The Henry Kaiser Family Foundation Website. www.statehealthfacts.org. Accessed 12/18/07

[6] OHSU.

[7] Institute for Clinical Systems Improvement (ICSI). *Technology Assessment Report: Prenatal Ultrasound as a Screening Test*. Bloomington, MN. (2002).

[8] United States Preventive Services Task Force (USPSTF). *Guide to Clinical Preventive Services. Chapter 36: Screening Ultrasound in Pregnancy*. Williams and Wilkins, Baltimore, MD. (1998).

[9] Institute for Clinical Systems Improvement (ICSI). *Health Care Guideline: Routine Prenatal Care*. Bloomington, MN. (2007).

[10] UpToDate, Inc. *Indications for Diagnostic Obstetrical Ultrasound Examination*. Waltham, MA. (2007).

[11] <http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=dhs16_137814>

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United States Preventive Services Task Force (USPSTF). *Guide to Clinical Preventive Services. Chapter 36: Screening Ultrasound in Pregnancy*. Williams and Wilkins, Baltimore, MD. (1998). <http://www.ahrq.gov/clinic/2ndcps/ultrason.pdf>

Veterans Health Administration, Department of Defense. *DoD/VA Clinical Practice Guideline for the Management of Uncomplicated Pregnancy*. Washington, DC. (2002).

Table 1: Evidence Consulted

Organization/Title/Year **Method to Analyze Evidence**	**Scope**	**Objectives**	**Methods to Make Recommendations /Conclusions**
AHRQ/Duke EPC 2002 (Federally-Funded University Research Organization) **Systematic Review**	Testing Management Intervention	To assess the literature on the benefits, risks, and costs of different strategies for managing prolonged pregnancy in order to avoid adverse perinatal and maternal outcomes.	Expert Consensus
Cochrane Collaboration 1998 (International Non-Profit Research Organization) **Systematic Review**	Screening Diagnosis Evaluation Prevention	To assess the use of routine (screening) ultrasound compared with the selective use of ultrasound in early pregnancy (i.e. before 24 weeks).	Expert Opinion
ECRI Institute 2003 (Independent Non-Profit Research Organization) **Systematic Review** **Meta-Analysis**	Screening Diagnosis Evaluation Prevention	To examine the effects of routine ultrasound scanning on various pregnancy outcomes.	Expert Consensus
Finnish Medical Society Duodecim 2004 (Medical Organization) **Systematic Review**	Diagnosis Evaluation Prevention	To collect, summarize, and update the core clinical knowledge essential to ultrasound scanning during pregnancy, and to describe the scientific evidence underlying the given recommendations.	Expert Consensus
Institute for Clinical Systems Improvement (ICSI) – Guideline 2007 (Non-Profit Quality Organization) **Systematic Review**	Screening Diagnosis Evaluation Intervention	To assist clinicians by providing an analytical framework for the evaluation and treatment of patients for routine prenatal care.	Expert Consensus
Institute for Clinical Systems Improvement (ICSI) – Technology Assessment 2002 (Non-Profit Quality Organization) **Systematic Review**	Screening Diagnosis Evaluation Prevention	To assist clinicians by providing a scientific assessment, through review and analysis of medical literature, of the safety and efficacy of prenatal ultrasound as a screening test.	Expert Consensus

Organization/Title/Year **Method to Analyze Evidence**	**Scope**	**Objectives**	**Methods to Make Recommendations /Conclusions**
National (UK) Collaborating Centre for Women's and Children's Health 2003 (UK Government-Funded Guideline Development Organization) **Systematic Review** **Meta-Analysis**	Counseling Evaluation Management Risk Assessment Screening Treatment	To offer information on best practice for baseline care of all pregnancies and comprehensive information on the antenatal care of the healthy woman with an uncomplicated singleton pregnancy. To provide evidence-based information for clinicians and pregnant women to make decisions about appropriate treatment in specific circumstances.	Expert Consensus
Oregon Health & Science University (OHSU) Center for Evidence-Based Policy 2006 (University Research and Policy Organization) **Systematic Review**	Screening Diagnosis Evaluation Prevention	To evaluate the safety and efficacy of screening ultrasound in uncomplicated pregnancy.	Expert Opinion
U.S. Preventive Services Task Force (USPSTF) 1998 (Federal Government Organization) **Literature Review**	Screening Diagnosis Evaluation Prevention	On behalf of the U.S. Public Health Service, to rigorously evaluate clinical research in order to assess the merits of ultrasonography in pregnancy.	Expert Consensus
Veterans Health Administration 2002 Federal Government Organization) **Systematic Review**	Evaluation Management Prevention Risk Assessment Screening	To provide a scientific evidence-base for practice interventions and evaluations. To enhance patient education so that pregnant women and their providers will each be aware of the specific expectations for every visit, thus promoting a partnership with a common goal of a healthy infant and mother. To improve patient and provider satisfaction with antenatal care from initial encounter in the clinic through parturition by providing an overview of screening and monitoring options as well as discussion about general clinical approaches to uncomplicated pregnancy. To change the traditional interval-based visit template to a system with specific gestational age visits, each having a specific well-defined goal and objectives.	Expert Consensus

APPENDIX A:
HSAC Process for Summarizing Evidence

Background: HSAC, in conjunction with the DHS Medical Director, is charged with advising the Department on clinical issues to inform decision-making on coverage and benefit policy. Where applicable, DHS produces summaries of existing clinical evidence to ensure that these decisions are based on the most up-to-date and reliable clinical evidence as well as the expertise of the Council's members.

Sources: The key sources used to gather evidence is gathered are summarized below:

- **Medicaid-Specific Collaborations:** Two key organizational collaborations provide a starting point for the evaluation of topics, helping to frame clinical questions and serving as channels for consultation with other states' programs in making evidence-based coverage decisions.
    - Medicaid Evidence-Based Decisions (MED) Project – A collaboration of state Medicaid programs housed at the Center for Evidence-Based Policy at Oregon Health & Science University. MED Project creates reports and recommendations based upon clinical evidence, provides staff support and facilitates knowledge sharing between states.
    - AHRQ/AcademyHealth Medicaid Medical Directors' Learning Network – A forum for the sharing of research and experience among medical directors in state Medicaid programs across the country.
- **Keyword Searches:** Topical keyword searches are then performed, searching for clinical guidelines and relevant peer-reviewed articles using the following sources:
    - AHRQ National Guidelines Clearinghouse – A clearinghouse of recommended guidelines from medical specialty societies, private non-profit organizations, and evidence-based practice centers.
    - The Cochrane Library – An international database of clinical practice guidelines. (Access to full-text resources is somewhat limited currently.)
    - PubMed and Medline – Medical/health sciences bibliographic databases.
- **Resources Accessed Directly:** Other sources are routinely accessed directly in search of clinical guidelines and peer-reviewed articles:
    - AHRQ Evidence-Based Program – A repository of rigorous clinical reports from grant-funded evidence-based practice centers across the U.S. and Canada.
    - Institute for Clinical Systems Improvement (ICSI) – A locally-based, nationally recognized collaboration of health care organizations that identifies best clinical practices and facilitates their implementation.
    - Technology Assessments:
        - Blue Cross and Blue Shield Association Technology Evaluation Center
        - ECRI Institute (Access provided through the MED Project)
        - ICSI

Process: After information is gathered and reviewed, sources are chosen with a preference for clinical practice guidelines (from professional organizations or independent non-profits), meta-analyses and systematic reviews, supplemented by quality peer-reviewed primary articles. Preference is also given to the most up-to-date evidence available. Summary documents are then created, providing brief background and context for the clinical issue, the amount, quality, and reliability of the evidence, and proposed action to be taken based upon that evidence. These documents are reviewed internally among DHS staff (including physicians) before coming before HSAC. HSAC uses these summary documents as a starting point for discussion around the issue in question, drawing upon their assessment of the evidence and their clinical expertise to advise DHS.

Shared Decision Making

Health Services Advisory Council

Evidence Summary

November 19, 2009

Minnesota Department of **Human Services**

Abstract

While some positive results from the use of patient decision aids (PtDAs) and shared decision-making (SDM) are encouraging, the vast majority of clinical trials involving PtDAs and SDM have not shown significant results. Lack of definition and standardization regarding currently available tools, coupled with concerns regarding their keeping current with the scientific literature, pose problems to the widespread integration of these tools beyond a research setting. While the intent of PtDAs and SDM is laudable, there are many unanswered questions regarding how best to use these tools. Concern regarding premature requirements for SDM highlights a risk of provider and patient backlash, despite potential benefits to both. There is now an active, community-wide multi-stakeholder group (the Minnesota Shared Decision Making Collaborative), that is working to develop, implement, and evaluate SDM in medical practices throughout Minnesota. It is suggested that policies related to SDM focus on facilitating and evaluating the results of this collaborative work rather than mandating or requiring SDM.

Background/Context

Policy Context

In the 2008-2009 Minnesota legislative session, the following law was passed (256B.0625, subdivision 3c): **Patient Centered Decision Making**: The Health Services Policy Committee shall study approaches to making provider reimbursement under the Medical Assistance, MinnesotaCare, and General Assistance Medical Care (GAMC) programs contingent on patient participation in a patient-centered decision-making process, and shall evaluate the impact of these approaches on health care quality, patient satisfaction, and health care costs. The committee shall present findings and recommendations to the commissioner and the legislative committees with jurisdiction over health care by January 15, 2010.

Background

Many decisions in health care are "preference-sensitive," defined as having the best choice dependent on the patient's values or preferences for the benefits, harms, and scientific uncertainties of each option (Wennberg et al, 2002). These decisions do not have clear answers because the benefit/harm ratios are either scientifically uncertain or are sensitive to patients' values. There can be wide variations in practice patterns in the use of preference-sensitive options. For example, the likelihood of having a lumpectomy for early stage breast cancer varied regionally between 12% and 48% among Medicare women (Center for the Evaluative Clinical Sciences, 2007).

When the "best" therapeutic option is unclear, a patient-centered or shared decision-making (SDM) style of counseling has been advocated (O'Connor et al, 2004). This involves practitioners communicating personalized information on options, outcomes, probabilities, and scientific uncertainties, and patients communicating the personal value or importance they place on benefits versus harms so that agreement on the best strategy can be reached. Shared decision-making is often positioned as a "middle ground" between paternalism (i.e., physicians make the decisions) and informed choice (i.e., patients make the decisions) (Makoul et al, 2005). To facilitate the process, evidence-based patient decision aids (PtDAs) have been developed as adjuncts to counseling.

PtDA development has utilized diverse formats including print, video and audio media, have been administered in self- or practitioner-administered situations, and have been used in one-on-one or group situations. There are three key elements common to the design of PtDAs: 1) Information provision, 2) values clarification, and 3) guidance in deliberation and communication (O'Connor, 2004).

With the rapid proliferation of these tools, the International Patient Decision Aids Collaboration (IPDAS) has reached agreement on criteria for judging the quality of PtDAs (O'Connor, 2007). IPDAS, a network of more than 100 researchers, practitioners, patients, and policy makers from 14 countries, has developed a checklist of criteria for PtDAs that addresses three domains of quality: clinical content, the development process, and effectiveness. These are listed as follows (Elwyn et al, 2006):

1. Content
    a. Provide information about options in sufficient detail for decision making?
    b. Present probabilities of outcomes in an unbiased and understandable way?
    c. Include methods for clarifying and expressing patient's values?
    d. Include structured guidance in deliberation and communication?
2. Development Process
    a. Present information in a balanced manner?
    b. Have a systematic development process?
    c. Use up-to-date scientific evidence that is cited in a reference section or technical document?
    d. Disclose conflicts of interest?
    e. Use plain language?
    f. Meet additional criteria if the patient decision aid is internet based?
    g. Meet additional criteria if stories are used in the patient decision aid?
3. Effectiveness
    a. Does the patient decision aid ensure decision making is informed and values based?

Purpose of this Document

The purpose of this document is:

- To evaluate the efficacy of shared decision-making and patient decision aids on health care quality, patient satisfaction, and health care costs;
- To discuss the current level of effectiveness of SDM and PtDAs in clinical practice outside of the research environment; and
- To present recommendations for policy options to promote the use of SDM in clinical practice.

Summary of the Evidence

Three systematic reviews (SR) of the effects of shared decision making and/or patient decision aids were identified for analysis. These are: a 2009 Cochrane Collaboration SR evaluating 55 studies on 23 screening or treatment decisions, a SR evaluating 11 studies on SDM for prostate-specific antigen testing, and a 2007 meta-analysis by the American Society for Clinical Oncology evaluating 11 studies on SDM for early-stage breast cancer. In addition, a number of studies highlighting challenges related to utilization of decision aids in clinical practice were included in this analysis. The findings are described, below.

Cochrane Collaboration 2009

A recently updated systematic review from the Cochrane Collaboration evaluated 55 randomized clinical trials (RCTs) from seven countries using 51 separate decision aids that evalulated 23 different screening or treatment decisions. (O'Connor, 2009). Results of RCTs were pooled using mean differences (MD) and relative risk (RR) using a random effects model.

According to this review, decision aids were correlated with better results related to patient knowledge and indecision, but no difference was found related to anxiety or decisional regret. Regarding health care quality and costs, decision aids were associated with statistically significant differences for PSA testing and use of Hepatitis B vaccines and menopausal hormones. Findings were mixed for complications of back pain, general health, and physical and role functions and status. No statistical difference was found related to patient adherence with several therapies, patient preference for a number of therapeutic options, or health outcomes related to 12 different measures.

The SR also evaluated the impact of decision aids on healthcare system. No statistical difference was found on overall cost, resource use, and provider and patient satisfaction. Results were mixed regarding changes in consultation length. Pooled results showed differences related to patient preference for less invasive options to surgery, but results of individual studies were mixed. The large heterogeneity of the studies warrants caution when interpreting this outcome.

More detailed findings from this systematic review can be found in Appendix A.

Elsevier 2004

This systematic review of the uptake of prostate-specific antigen (PSA) testing following use of PtDAs included 7 decision aids and 11 evaluations (Evans, 2005). The meta-analysis showed the following:

a) There was a significant reduction in probability of PSA testing after a decision aid (-3.5%; 95% CI 0.0 to 7.2%; $p = 0.50$);
b) Improvements were gained in knowledge within two weeks after a decision aid (19.5%; 95% CI 14.2 to 24.8%; $p < 0.001$). The effect on knowledge was less pronounced within 12-18 months after a decision aid (3.4%; 95% CI -0.7 to 7.4%; $p = 0.10$).

American Society of Clinical Oncology 2007

This meta-analysis pooled the relative risk for 11 studies (randomized and non-randomized) designed to assess the effect of decision aids on the choice for surgery and knowledge of surgical therapy among women with early-stage breast cancer (Waljee et al, 2007). Results were mixed regarding patient preference for therapy, knowledge, and decisional conflict. More detailed results can be found in Appendix B.

Additional Studies

Quality of PtDAs
According to a systematic review regarding whether PtDAs meet IPDAS standards, 38 of 55 RCTs used at least one measure that mapped onto an IPDAS effectiveness criterion (O'Connor, 2007). According to the study, future trials need to use a minimum data set of IPDAS evaluation measures.

An earlier SR of PtDAs (Feldman-Stewart 2006) found that of 68 treatment PtDAs and 30 screening PtDAs identified, 17% of treatment PtDAs and 47% of screening PtDAs did not report any external consultation in their development. Content evaluations showed that 1) treatment PtDAs frequently omit describing the procedure(s) involved in the treatment options and 2) screening PtDAs frequently focus on false positives but not false negatives. About 1/2 treatment PtDAs reported probabilities with a greater emphasis on potential benefits than harms. Similarly, screening PtDAs were more likely to provide false-positive than false-negative rates.

Lack of Definition of Shared Decision Making
Much of the research to date has been done on the use of PtDAs but does not address the extent to which a shared decision making process (which could include PtDAs, counseling, and other modalities) can affect patient decisions. According to one researcher (Makoul, 2006), the concept of SDM has been variably, and often loosely, defined. According to Makoul, this lack of synthesis is problematic for several reasons. First, inconsistent conceptual definitions lead to inconsistent measurement of SDM. Second, the lack of a core definition of SDM complicates efforts to identify the relationships between SDM and outcome measures. Third, variable instantiations of SDM definitions make comparisons across studies difficult, if not impossible.

Barriers to Use
Potential barriers to the use of PtDAs include practitioner concerns about the PtDAs' comprehensiveness and up-to-datedness (Graham 2003). According to one study (O'Donnell, 2006), with the ever-shortening shelf life of scientific evidence, it is important that PtDA developers be closely linked to those who produce, summarize, and analyze evidence. Another potential barrier is lack of awareness of existing PtDAs for a particular clinical decision. While practitioners may agree with involving patients in health-related decisions, they do not always acquire the knowledge or skills to successfully practice shared decision making (Holmes-Rovner, 2000).

According to one researcher (O'Donnell, 2006), there is no evidence on the assessment of readability of PtDAs and their suitability for particular audiences. Future research is required on how PtDAs work to improve decision quality for people who vary by demographic characteristics (age, sex, education, ethnicity) and baseline decision needs (stage of decision making, preference for participation in decision making) for better health outcomes.

Per O'Donnell (2006), the organizational culture can either hinder or facilitate the uptake of PtDAs. In addition, structural barriers and pre-existing clinical care processes have all been cited as barriers in the uptake and/or appropriate timing of PtDA administration into the process of routine care.

A systematic review (Gravel, 2006) was performed on the barriers and facilitators to implementing shared decision making in clinical practice as perceived by health professionals. Thirty-one publications covering 28 unique studies were included. Overall, the vast majority of participants (n=2784) were physicians (89%). The three most often reported barriers were: time constraints (18/28), lack of applicability due to patient characteristics (12/28), and lack of applicability due to the clinical situation (12/28). The three most often reported facilitators were: provider motivation

(15/28), positive impact on the clinical process (11/28), and positive impact on patient outcomes (10/28).

Discussion

While some results from the use of PtDAs and SDM are encouraging, the vast majority of clinical trials involving PtDAs and SDM have not shown significant results. Findings tended to be strongest regarding increases in patient knowledge, but these gains diminished over time. Results were mixed regarding the effect of decision aids on patient function or status. While there was a significant, overall trend showing the influence of decision aids on patient preference for less-invasive surgical options, the large heterogeneity of the studies warrants caution when interpreting this outcome.

Studies have indicated that most currently available decision aids do not meet international standards for quality. A lack of definition regarding shared decision making complicates its utilization in a clinical setting. Additional concerns include: challenges in keeping tools up-to-date, suitability of PtDAs for diverse populations, and challenges associated with organization culture. Facilitators to implementation include: provider motivation, positive impact on the clinical process, and positive impact on patient outcomes.

For decisions in health care that are preference sensitive, a shared decision making process can help patients to reach a decision that is both informed and aligned with their values. The literature shows that this field is still in development. More research is needed to advance the successful integration of shared decision making processes and tools beyond a research setting.

Policy Options

The Minnesota Shared Decision Making Collaborative (MSDMC) has produced a summary report on SDM that describes the history of SDM in Minnesota and provides legislative policy recommendations regarding the promotion of SDM in Minnesota (MSDMC, 2009). The report is attached to this HSAC Evidence Summary. The policy recommendations from the MSDMC for consideration by HSAC are as follows:

Options for the next two years

1. **Pilot studies** SDM pilot studies in clinical settings will help us learn more rapidly how best to provide this service. The health care home might be a good focus for an SDM pilot study focused on primary care services. Pilot studies provide a valuable opportunity to explore and identify the best approach to implementing SDM. Issues that need to be addressed in pilot studies include 1) how to reliably identify and engage patients in SDM; 2) how best to provide decision support for different kinds of health decisions (e.g., preventive services, acute care, and chronic care); and 3) how or whether to compensate providers for these services. Pilot studies may not require substantial resources, especially if they can be funded with research grants.
2. **Community education and social marketing** A state-wide campaign to raise awareness about the importance of practice pattern variation, patient preferences, and patient participation in medical decision making could add substantial value. We are eager to work with the State on such a project.

Options requiring developmental work

3. **Creating a legal incentive for SDM** Modifying Minnesota law to raise the level of evidence required for plaintiffs to prevail in a "failure-to-inform" malpractice suit when SDM was provided, while maintaining the current level of evidence required for informed consent, might help accelerate adoption of SDM. We are in the process of working with the legal community to determine how best to effect this in Minnesota. Any legislation on this should wait until after developmental work has been completed.
4. **SDM decision quality measures** The MSDMC is working with Minnesota Community Measurement to develop valid and reliable measures of decision making quality. Once these measures have been shown to be robust and valid, state support in the form of DHS and SEGIP participation in pay-for-performance or other provider incentive programs based on these measures will support SDM adoption.

Options not recommended

5. **Mandated SDM** Mandating or requiring SDM as a condition of payment runs a high risk of being perceived by both patients and physicians as government interference in the physician-patient relationship. This may interfere dramatically with the adoption of SDM. We are also confident that through the collaborative process we will be able to implement SDM in Minnesota without legislative mandates.
6. **Paying providers for SDM** We believe it is too early to link SDM to fee-for-service (FFS) payment. For one thing, SDM may reduce provider resources required to perform effective patient education. In addition, pay-for-performance programs have succeeded in promoting evidence-based care and other clinical quality improvements, and may be effective for SDM. Finally, paying FFS for SDM may prematurely close off other promising approaches to provider compensation for SDM such as case rates or total cost of care models.

Policy Recommendation

The policy recommendations from HSAC to the Legislature are as follows:

Options Recommended

1. **Implement Pilot Studies** Develop pilot studies regarding the use of SDM in clinical settings. These studies should be conducted in a way that allows results from SDM and care within a health care home to be quantified independently. Issues to be addressed in pilot studies include, but are not limited to: 1) how to reliably identify and engage patients in SDM; 2) how best to provide decision support for different kinds of health decisions (e.g., preventive services, acute care, and chronic care); and 3) how or whether to compensate providers for these services.
2. **Develop a Core Archetype of the SDM Process** Utilize the findings from pilot studies to develop a model for implementing SDM in clinical settings.

Options Not Recommended

3. **Mandate SDM** It is not recommended to mandate SDM. Mandating or requiring SDM as a condition of payment may create the perception by both patients and physicians as government interference in the physician-patient relationship. This may interfere dramatically with the adoption of SDM in clinical practice.
4. **Pay Providers for SDM** At this time, it is not recommended that providers be paid additionally for SDM activities. The literature does not show that SDM has an overall impact on cost and resource use in the clinic. While SDM is the type of activity that overall payment reform would recognize, fee-for-service payment for SDM is not recommended.
5. **Implement Payment Incentives Based on SDM Quality Measures** It is premature, in advance of successful pilot studies and the development of reliable measures of SDM quality, to implement payment incentives for adherence to SDM quality measures.
6. **Create a Legal Incentive for SDM** Until the ramifications of modifying Minnesota law to develop a higher evidentiary standard for "failure to inform" malpractice law suits where SDM is utilized, it is not recommended that this be implemented at this time. The MSDMC is currently researching this option. Any legislation on this should wait until after developmental work has been completed.

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Appendix A: Cochrane Study Results

Patient Knowledge and Satisfaction

a) **Difference Found:** These areas showed a significant difference between patients with and without PtDAs.
   - Lower decisional conflict related to feeling uninformed (MD -8.3%; 95% CI -11.9 to -4.8) (10 trials);
   - Lower decisional conflict related to feeling unclear about personal values (MD -6.4%; 95% CI -10.0 to -2.7);
   - Reduced the proportion of people who were passive in decision making (RR 0.6; 95% CI 0.5 to 0.8);
   - Reduced the proportion of people who remained undecided post-intervention (RR 0.5; 95% CI 0.3 to 0.8).
   - Higher average knowledge scores (MD 15.2%; 95% CI 11.7 to 18.7) (18 studies);
   - When simpler decision aids were compared to more detailed decision aids, the detailed PtDAs were correlated with higher average knowledge scores (MD 4.6%; 9%% CI 3.0 to 6.2) (9 studies);
   - Exposure to a decision aid with probabilities resulted in a higher proportion of people with accurate risk perceptions (RR 1.6; 95% CI 1.4 to 1.9). The effect was stronger when results were measured quantitatively (RR 1.8; 95% CI 1.4 to 2.3) (8 studies) than qualitatively (RR 1.3; 95% CI 1.1 to 1.5) (3 studies).

b) **No Difference Found:** Decision aids were not statistically significantly associated with differences in these areas:
   - State anxiety[1] (breast cancer – 2 studies; hypertension – 1 study; breast cancer – 10 studies; prenatal screening – 3 studies; pregnancy termination – 1 study; prostate cancer – 1 study; BPH – 1 study; HRT – 1 study; menorrhagia treatment – 1 study);
   - Decisional regret (1 study)
   - Trait anxiety[2] – prostate cancer treatment (1 study)

Health Care Quality and Costs

a) **Difference Found:** Use of decision aids were statistically significantly associated with differences in these areas:
   - PSA testing (RR 0.8; 95% CI 0.66 to 0.98; p = 0.03) (5 studies)
   - Use of Hepatitis B vaccination (*statistics not given)*
   - Use of menopausal hormones (RR 0.7; 95% CI 0.6 to 1.0, p = 0.04) (3 studies)

b) **Indeterminate Findings:** Use of decision aids were associated with mixed results in these areas
   - Complications of back pain - 1 study (back pain severity) found significant differences (p value not given); 5 studies (% working, % missed 1+ day within past month, leg pain severity, seeking compensation, and satisfied with symptoms) found no difference.
   - General health - 1 study (p = 0.02) found differences at baseline; no difference was found at 3, 6 and 12 month follow-ups.
   - Physical function 1 study (p = 0.02) found differences at baseline; no difference was found at 3 and 6 months follow-ups. Four other studies found no difference.
   - Role emotional – 1 study (p = 0.01) found a difference; one other study found no difference.

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[1] State Anxiety: short-term anxiety in response to external stimuli.
[2] Trait Anxiety: long-term anxiety that is a relatively stable aspect of the personality.

- Role function - 1 study (p = 0.04) found a difference; two other studies found no difference.
- Social function - 1 study (p = 0.02) found a difference at baseline; no difference was found at 3, 6 and 12 month follow-ups. Two other studies found no difference.

c) **No Difference Found:** Decision aids were not statistically significantly associated with differences in these areas:
- Adherence with the chosen option (warfarin versus aspirin, oral bisphosphonate medication, blood pressure medication, hormone replacement therapy)
- Antithrombotic therapy for atrial fibrillation versus usual care
- Preference for adjuvant chemotherapy for breast cancer
- Uptake of pre-operative autologous blood donation
- Uptake of medication for hypertension
- Vaginal birth following previous cesarean section
- Health outcomes
  - Angina (10 studies)
  - Bodily pain (3 studies)
  - Breast cancer genetic testing (4 studies)
  - Colon cancer screening (3 studies)
  - Depression (2 studies)
  - Energy (2 studies)
  - Functional status (1 study)
  - Health utilities[3] (2 studies)
  - Menstrual symptoms (3 studies)
  - Mental function (3 studies)
  - SF-36 all dimensions[4] (2 studies)
  - Urinary symptoms (4 studies)

Healthcare System Effects

- Four trials found no statistically significant impact of decision aids on overall cost and resource use;
- Changes in consultation length were inconsistent across studies;
- Patient and physician perception of the quality, usefulness and directiveness of the consultation session did not differ significantly when using PtDAs;
- Studies were pooled to determine whether use of PtDAs reduced the participant's stated preference to have surgery and/or reduced the number of surgeries that actually occurred. Eight studies evaluated the effect of PtDAs on a total of seven different major surgical interventions. These findings are shown below in Figure 1. According to the Cochrane review, overall results are significant for the pooled studies. Given the heterogeneity of the studies used in this analysis (I^2 = 73%), these results should be interpreted with caution.

[3] Health Utility Index: forms a single composite score based on self-reported status on eight attributes of functional ability.
[4] SF-36: A survey of patient health with equal weight given to vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, and mental health.

Figure 1A: Results from Cochrane 2009 – Patient Preference for Surgery versus Conservative Option. Intention to Treat Analysis.

	A	B	C	D	E	F	G	H	I
Intention to Treat	**Decision Aid**			**Usual Care**			**Absolute Effect**	**Risk Ratio**	**Significance**
	n	N	Event rate %	n	N	Event rate%			
Kennedy	83	300	27.7%	101	298	33.9%	-9%	0.78	
Morgan	45	120	37.5%	63	120	52.5%	-14%	0.79	P = .01
Murray	6	57	10.5%	1	55	1.8%	9%	5.33	
Vuorma	98	184	58.3%	88	179	49.2%	4%	1.08	
Bernstein	25	65	38.5%	28	53	52.8%	-17%	0.70	
Auvinen	60	104	57.7%	91	106	85.8%	-33%	0.64	P = .001
Barry	8	104	7.7%	16	123	13.0%	-6%	0.56	
Whelan	6	94	6.4%	26	107	24.3%	-18%	0.26	Not given
	330	1028		414	1041		-9%	0.75	95% CI 0.59, 0.94

Figure 1B: Results from Cochrane 2009 – Patient Preference for Surgery versus Conservative Option. As Treated Analysis.

	A	B	C	D	E	F	G	H	I
As Treated	**Decision Aid**			**Usual Care**			**Absolute Effect**	**Risk Ratio**	**Significance**
	n	N	Event rate %	n	N	Event rate%			
Kennedy	82	253	32.4%	101	244	41.4%	-9%	0.78	
Morgan	45	86	52.3%	63	95	66.3%	-14%	0.79	P = .06
Murray	6	54	11.1%	1	48	2.1%	9%	5.33	
Vuorma	98	184	53.3%	88	179	49.2%	4%	1.08	
Bernstein	25	61	41%	28	48	58.3%	-17%	0.70	
Auvinen	60	103	58.3%	91	100	91%	-33%	0.64	P = .19
Barry	8	103	7.8%	16	116	13.8%	-6%	0.56	
Whelan	6	94	6.4%	26	107	24.3%	-18%	0.26	P = .03
	330	938	35.2%	414	937	44.2%	-9%	0.75	95% CI 0.59, 0.94

Appendix B: Oncology Results

Final Treatment Decision
Two RCTs measured final treatment decision; one of these showed a statistically significant difference ($p < .05$) between treatment arms, favoring breast conserving surgery. The other RCT did not show a statistical difference. Two non-randomized trials measured final treatment decision; one was not significant, the other showed a statistically significant difference ($p < .05$) between treatment arms favoring mastectomy.

Knowledge
Seven studies assessed patient knowledge. Three studies (2 RCTs and 1 non-RCT) showed a significant increase in knowledge after use of a decision aid. Four studies (1 RCT and 3 non-RCTs) did not show a significant increase in knowledge.

Decisional Conflict
Four studies assessed differences in decisional conflict. One RCT and 1 non-RCT showed a significant difference ($p < 0.05$); 1 RCT and 1 non-RCT did not.

Convenience and Ease of Use
The report comments on convenience and ease of use but is unclear regarding the unit of analysis (patient or study) for the findings.

APPENDIX C:
HSAC Process for Summarizing Evidence

Background: HSAC, in conjunction with the DHS Medical Director, is charged with advising the Department on clinical issues to inform decision-making on coverage and benefit policy. Where applicable, DHS produces summaries of existing clinical evidence to ensure that these decisions are based on the most up-to-date and reliable clinical evidence as well as the expertise of the Council's members.

Sources: The key sources used to gather evidence is gathered are summarized below:

- **Medicaid-Specific Collaborations:** Two key organizational collaborations provide a starting point for the evaluation of topics, helping to frame clinical questions and serving as channels for consultation with other states' programs in making evidence-based coverage decisions.
    - Medicaid Evidence-Based Decisions (MED) Project – A collaboration of state Medicaid programs housed at the Center for Evidence-Based Policy at Oregon Health & Science University. MED Project creates reports and recommendations based upon clinical evidence, provides staff support and facilitates knowledge sharing between states.
    - AHRQ/AcademyHealth Medicaid Medical Directors' Learning Network – A forum for the sharing of research and experience among medical directors in state Medicaid programs across the country.
- **Keyword Searches:** Topical keyword searches are then performed, searching for clinical guidelines and relevant peer-reviewed articles using the following sources:
    - AHRQ National Guidelines Clearinghouse – A clearinghouse of recommended guidelines from medical specialty societies, private non-profit organizations, and evidence-based practice centers.
    - The Cochrane Library – An international database of clinical practice guidelines. (Access to full-text resources is somewhat limited currently.)
    - PubMed and Medline – Medical/health sciences bibliographic databases.
- **Resources Accessed Directly:** Other sources are routinely accessed directly in search of clinical guidelines and peer-reviewed articles:
    - AHRQ Evidence-Based Program – A repository of rigorous clinical reports from grant-funded evidence-based practice centers across the U.S. and Canada.
    - Institute for Clinical Systems Improvement (ICSI) – A locally-based, nationally recognized collaboration of health care organizations that identifies best clinical practices and facilitates their implementation.
    - Technology Assessments:
        - Blue Cross and Blue Shield Association Technology Evaluation Center
        - ECRI Institute (Access provided through the MED Project)
        - ICSI

Process: After information is gathered and reviewed, sources are chosen with a preference for clinical practice guidelines (from professional organizations or independent non-profits), meta-analyses and systematic reviews, supplemented by quality peer-reviewed primary articles. Preference is also given to the most up-to-date evidence available. Summary documents are then created, providing brief background and context for the clinical issue, the amount, quality, and reliability of the evidence, and proposed action to be taken based upon that evidence. These documents are reviewed internally among DHS staff (including physicians) before coming before HSAC. HSAC uses these summary documents as a starting point for discussion around the issue in question, drawing upon their assessment of the evidence and their clinical expertise to advise DHS.

APPENDIX D:
Principles for Assessing the Quality of Evidence

AMSTAR (Assessment of Multiple Systematic Reviews)[1]

AMSTAR is a measurement tool created to assess the methodological quality of systematic reviews. Each of the questions below is answered with one of the following:
_ Yes
_ No
_ Can't answer
_ Not applicable

1. Was an 'a priori' design provided?
The research question and inclusion criteria should be established before the conduct of the review.

2. Was there duplicate study selection and data extraction?
There should be at least two independent data extractors and a consensus procedure for disagreements should be in place.

3. Was a comprehensive literature search performed?
At least two electronic sources should be searched. The report must include years and databases used (e.g. Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated and where feasible the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found.

4. Was the status of publication (i.e. grey literature) used as an inclusion criterion?
The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc.

5. Was a list of studies (included and excluded) provided?
A list of included and excluded studies should be provided.

6. Were the characteristics of the included studies provided?
In an aggregated form such as a table, data from the original studies should be provided on the participants, interventions and outcomes. The ranges of characteristics in all the studies analyzed e.g. age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported.

7. Was the scientific quality of the included studies assessed and documented?
'A priori' methods of assessment should be provided (e.g., for effectiveness studies if the author(s) chose to include only randomized, double-blind, placebo controlled studies, or allocation concealment as inclusion criteria); for other types of studies alternative items will be relevant.

8. Was the scientific quality of the included studies used appropriately in formulating conclusions?
The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations.

9. Were the methods used to combine the findings of studies appropriate?
For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e. Chi-squared test for homogeneity, I2). If heterogeneity exists a random effects model should be used and/or the clinical appropriateness of combining should be taken into consideration (i.e. is it sensible to combine?).

10. Was the likelihood of publication bias assessed?
An assessment of publication bias should include a combination of graphical aids (e.g., funnel plot, other available tests) and/or statistical tests (e.g., Egger regression test).

11. Was the conflict of interest stated?
Potential sources of support should be clearly acknowledged in both the systematic review and the included studies.

[1] Shea, BJ et al. Development of AMSTAR: A Measurement Tool to Assess the Methodological Quality of Systematic Reviews. *BMC Medical Research Methodology* (2007); 7(10).

Cochrane Collaboration: Criteria List for the Methodological Quality Assessment of Individual Studies[2]

The Cochrane criteria assess the quality and internal validity of individual trials. Each of the questions below is answered with one of the following:

_ Yes
_ No
_ Don't Know

1. **Was the method of randomization adequate?**
   A random (unpredictable) assignment sequence. Examples of adequate methods are computer generated random number table and use of sealed opaque envelopes. Methods of allocation using date of birth, date of admission, hospital numbers, or alternation should not be regarded as appropriate.

2. **Was the treatment allocation concealed?**
   Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient.

3. **Were the groups similar at baseline regarding the most important prognostic indicators?**
   In order to receive a "yes", groups have to be similar at baseline regarding demographic factors, duration and severity of complaints, percentage of patients with neurological symptoms, and value of the main outcome measure(s).

4. **Was the patient blinded to the intervention?**
   The reviewer determines if enough information about the blinding is given in order to score a "yes".

5. **Was the care provider blinded to the intervention?**
   The reviewer determines if enough information about the blinding is given in order to score a "yes".

6. **Was the outcome assessor blinded to the intervention?**
   The reviewer determines if enough information about the blinding is given in order to score a "yes".

7. **Were cointerventions avoided or similar?**
   Cointerventions should either be avoided in the trial design or similar between the index and control groups.

8. **Was the compliance acceptable in all groups?**
   The reviewer determines if the if the compliance to the interventions is acceptable, based on the reported intensity, duration, number and frequency of sessions for both the index intervention and control intervention(s).

9. **Was the drop-out rate described and acceptable?**
   The number of participants who were included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and drop-outs does not exceed 20% for short-term follow-up and 30% for long-term follow-up and does not lead to substantial bias a "yes" is scored. (N.B. these percentages are arbitrary, not supported by literature.)

10. **Was the timing of the outcome assessment in all groups similar?**
    Timing of outcome assessment should be identical for all intervention groups and for all important outcome measurements.

11. **Did the analysis include an intention-to-treat analysis?**
    All randomized patients are reported/analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values) irrespective of noncompliance and co-interventions.

[2] van Tulder, M et al. Updated Method Guidelines for Systematic Reviews in the Cochrane Collaboration Back Review Group. *SPINE* (2003); 28(12): 1290-1299.

Sleep Studies for Adults

Health Services Advisory Council

Evidence Summary

April 10, 2008

Minnesota Department of **Human Services**

Background/Context

Sleep studies encompass a range of diagnostic and therapeutic interventions pertaining to sleep-related disorders. Principal among these is polysomnography, which is considered the "gold standard" test for the diagnosis of obstructive sleep apnea and a number of other sleep disorders. Polysomnography is an overnight sleep study in which three primary categories of physiologic signals are monitored while a patient sleeps: those that recognize sleep (electroencephalography, electrooculogram, electromyelogram), those that monitor cardiac arrhythmia (electrocardiogram), and those relating to respiration (airflow, thoracoabdominal effort, oximetry).[1]

It is estimated that 40 million Americans have some type of sleep disorder, with 30 million likely to have sleep apnea (of these 30 million, 28.5 million with sleep apnea are believed to be undiagnosed).[2] Obstructive sleep apnea/hypopnea syndrome is a clinical condition in which the upper airway collapses intermittently and repeatedly during sleep, leading to interrupted or reduced-quality sleep. In addition to reduced quality of life and daytime sleepiness, sleep apnea patients are at increased risk for motor vehicle accidents and cardiovascular disease.[3] The perceived underdiagnosis and increased awareness of sleep disorders, along with sleep apnea's intimate link with the obesity epidemic, has led to increased demand for sleep studies and treatments.[4] In the fee-for-service (FFS) Minnesota Health Care Programs (MHCP), the enrollment-adjusted reimbursement for sleep studies (driven heavily by polysomnography) increased nearly 180% from calendar years 2002 through 2006. Sleep testing for children and adolescents under the age of 18 currently requires authorization in FFS MHCP (using Blue Cross and Blue Shield of Minnesota medical necessity criteria, attached as *APPENDIX A*), while sleep studies are unmanaged in the adult population despite the fact that adults make up more than 80% of FFS utilization for these procedures.

"Although PSG [polysomnography] is accepted in North America as the gold standard test for the diagnosis of sleep apnoea it has never been independently validated. Observational studies indicate that PSG may be useful in the diagnosis of sleep apnoea although there is night-to-night variation in PSG reproducibility. Different centres also use different thresholds in the diagnosis of sleep apnoea."[5] However, predictive equations drawn from history and examination alone have largely not been useful in clinical practice, and while it is useful to exclude other causes of symptoms an exam alone cannot accurately diagnose sleep apnea.[6] In the climate of rapid growth in polysomnography utilization, some have questioned the clinical value of performing the test on all patients with daytime sleepiness. It is crucial to examine the evidence on indications for sleep testing to ensure that coverage policy reflects the population for whom these tests are most appropriate.

Summary of the Evidence

The evidence reviewed for this document includes four sets of clinical practice guidelines based on systematic literature reviews, two systematic reviews of the evidence used to formulate guidelines, and a narrative review. The scope of these documents varies somewhat. The guidelines focus on indications for polysomnography and the management of sleep apnea in adults, while the systematic reviews cover sleep testing more broadly. The literature and guidelines specific to portable monitors for home diagnosis of sleep apnea were also reviewed, and are summarized separately below.

The four sets of guidelines reached largely overlapping conclusions on the indications for polysomnography.

- A 2005 guideline from the American Sleep Disorders Association (ASDA) published in the journal *Sleep* concluded that polysomnography is routinely indicated for the diagnosis of sleep-related breathing disorders, but that an attended cardiorespiratory (Type 3) study may be an acceptable alternative for patients in the high-pretest-probability stratification group. Polysomnography is also recommended for CPAP titration in patients already diagnosed with sleep-related breathing disorders, with split-night studies preferred if certain criteria are met. Follow-up polysomnography (or Type 3 study) is recommended to assess treatment results. Other indications listed include neuromuscular disorders, suspected narcolepsy, parasomnias, and periodic limb movement disorder.

- The Scottish Intercollegiate Guidelines Network (SIGN) published a national guideline on the management of sleep apnea in adults in 2003. The Scottish guideline recommends limited sleep studies (including one or more of the following: oximetry, thoraco-abdominal respiratory movement and airflow, recordings of snoring, heart rate, or general airflow) as a first-line method of diagnosing sleep apnea rather than full channel polysomnography. SIGN also recommends that all patients and their partners complete an Epworth questionnaire (which assesses sleepiness), as well as undergo a physical exam to exclude other causes for the patient's symptoms.

- The Institute for Clinical Systems Improvement (ICSI) updated its guideline on the diagnosis and treatment of obstructive sleep apnea in adults in 2007. ICSI concluded that while polysomnography is the accepted standard test for sleep apnea and is indicated for suspected sleep disorders, selection of appropriate diagnostic tests must take into account the estimated pretest probability of the patient having sleep apnea. The guideline lists signs and symptoms that have been found to be predictive of sleep apnea in studies using logistic regression, and also recommends that split-night studies be performed whenever possible.

- A 1996 guideline from the Canadian Sleep Society and the Canadian Thoracic Society covered indications for sleep testing as well as staffing and technical standards. Listed indications for polysomnography were presented as four broad headings: disorders that produce a complaint of insomnia, disorders that produce a complaint of excessive sleepiness, parasomnias that intrude into or occur during sleep, and disorders of the timing of the main sleep period.

The systematic reviews assessed the evidence used to support guideline recommendations for sleep testing, and summarized the indications for sleep testing listed in those guidelines. The indications for polysomnography listed are the same as those listed above: diagnosis of sleep apnea,

neuromuscular disorders, certain insomnias, suspected narcolepsy, periodic limb movement disorder, and certain parasomnias. One of the systematic reviews assessed the strength of the evidence supporting 81 separate guideline recommendations:[7] 46 of the 81 recommendations were supported by evidence from primary studies (the remainder represented professional opinion or consensus). Of the

46 recommendations supported by studies, six represented "A" quality (from well-conducted, prospective, controlled studies), 15 represented "B" quality (from controlled studies and case series), and 25 represented "C" quality (from case series or studies with significant limitations). The reviewers concluded that the evidence supporting guideline recommendations was of relatively good quality for obstructive sleep apnea, and of reasonable quality and relevance for insomnia with suspected breathing disorders, insomnia with suspected periodic limb movement disorder, and insomnia and depression; the remainder of the indications listed in the guidelines would benefit from further high-quality studies.[8] The evidence supporting the guidelines is of varying quality, reflecting the ongoing controversy regarding the appropriate use of sleep studies.

Home Sleep Studies

Portable monitors to record sleep signals in the home have been proposed as an alternative to in-lab sleep testing. Because of the resources and technical expertise needed to perform polysomnography, home diagnosis has been advocated as a cost-effective alternative that may improve timely access to diagnostic testing for patients with suspected sleep apnea. However, the literature has largely failed to demonstrate the efficacy of in-home testing relative to laboratory polysomnography. A 2003 systematic review[9] commissioned by the American Academy of Sleep Medicine (AASM), the American College of Chest Physicians, and the American Thoracic Society resulted in guidelines recommending that portable monitoring devices not be used in unattended settings. A 2007 review[10] pointed out the varying results of using portable monitors in investigational settings, as well as their high failure rate and the need for repeat tests. Local carriers' coverage policies largely reflect this lack of evidence by refusing coverage for unattended and in-home sleep studies.

Professional consensus on home sleep testing appears to be shifting, however. At the end of 2007, the AASM Portable Monitoring Task Force published guidelines[11] recommending the in-home use of portable monitors as an alternative to polysomnography for patients with high pre-test probability of sleep apnea in the absence of significant co-morbidities. Based on a systematic review conducted by the Agency for Healthcare Research and Quality (AHRQ)[12] as well as its own assessment of the literature, the Centers for Medicare and Medicaid Services (CMS) recently expanded its national Medicare coverage determination to cover CPAP when beneficiaries are diagnosed by a positive polysomnography *or* an unattended home monitoring device.

Policy Option: Authorization

There are consistent indications in the literature for the use of polysomnography, and the guidelines provide a framework for its evidence-based application. Although polysomnography has not been independently validated, it is considered the diagnostic gold standard for obstructive sleep apnea. Further, other diagnostic methods (such as sleep history, pulse oximetry, and clinical predictive models based on symptoms) are considered inadequate on their own to diagnose sleep-related breathing disorders. DHS could draft evidence-based criteria and place sleep studies for adults on authorization in fee-for-service, as is currently required for the pediatric population.

[Authorization criteria available separately.]

Proposed Codes

CPT

95805 - Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness
95806 - Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, unattended by a technologist
95807 - Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist
95808 - Polysomnography; sleep staging with 1-3 additional parameters of sleep, attended by a technologist
95810 - Polysomnography; sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95811 - Polysomnography; sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bilevel ventilation, attended by a technologist

References

[1] Patil SP et al. Adult Obstructive Sleep Apnea: Pathophysiology and Diagnosis. *Chest* (2007);132: 325-37.

[2] Institute for Clinical Systems Improvement (ICSI). Health Care Guideline: Diagnosis and Treatment of Obstructive Sleep Apnea in Adults. Bloomington, MN. (2007).

[3] ibid.

[4] Patil SP et al.

[5] Scottish Intercollegiate Guidelines Network (SIGN). Management of Obstructive Sleep Apnoea/Hypopnoea Syndrome in Adults: A National Clinical Guideline. Edinburgh, Scotland. (2003).

[6] ibid.

[7] Hailey D and Tran K. Quality and Relevance of Evidence in Support of Guideline Recommendations for Sleep Laboratory Investigations. *International Journal of Technology Assessment in Health Care* (2005); 21(4):459-63.

[8] Canadian Coordinating Office for Health Technology Assessment. *A Review of Guidelines for Referral of Patients to Sleep Laboratories.* Ottawa, Ontario, Canada. (2005).

[9] Flemons WW et al. Home Diagnosis of Sleep Apnea: A Systematic Review of the Literature: An Evidence Review Cosponsored by the American Academy of Sleep Medicine, the American College of Chest Physicians, and the American Thoracic Society. *Chest* (2003);124(4):1543-79.

[10] Ahmed M. Portable Monitors in the Diagnosis of Obstructive Sleep Apnea. *Chest* (2007):132(5):1672-7.

[11] Collop NA et al. Clinical Guidelines for the Use of Unattended Portable Monitors in the Diagnosis of Obstructive Sleep Apnea in Adult Patients. *Journal of Clinical Sleep Medicine* (2007);3(7):737-47.

NOTE: This guideline is not included in the "evidence consulted" section below since the full version was not available to DHS staff at the time this document was created.

[12] Agency for Healthcare Research and Quality (AHRQ). Technology Assessment: Home Diagnosis of Obstructive Sleep Apnea-Hypopnea Syndrome. Rockville, MD. (2007).

Evidence Consulted

Agency for Healthcare Research and Quality (AHRQ). *Technology Assessment: Home Diagnosis of Obstructive Sleep Apnea-Hypopnea Syndrome.* Rockville, MD. (2007). <LINK TO FULL TEXT>

Ahmed M. Portable Monitors in the Diagnosis of Obstructive Sleep Apnea. *Chest* (2007);132(5):1672-7.

<LINK TO ABSTRACT>

Canadian Coordinating Office for Health Technology Assessment. *A Review of Guidelines for Referral of Patients to Sleep Laboratories.* Ottawa, Ontario, Canada. (2005). <LINK TO SUMMARY>

Centers for Medicare and Medicaid Services (CMS). *Decision Memo for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (CAG-00093R2).* Baltimore, MD. (2008). <LINK TO FULL TEXT>

Chesson AL et al. Practice Parameters for the Use of Portable Monitoring Devices in the Investigation of Suspected Obstructive Sleep Apnea in Adults. *Sleep* (2003);26(7):907-13. <LINK TO ABSTRACT>

Flemons WW et al. Home Diagnosis of Sleep Apnea: A Systematic Review of the Literature: An Evidence Review Cosponsored by the American Academy of Sleep Medicine, the American College of Chest Physicians, and the American Thoracic Society. *Chest* (2003);124(4):1543-79. <LINK TO FULL TEXT>

George CFP. Consensus Statement: Standards for Polysomnography in Canada. *Canadian Medical Association Journal* (1996);155(12):1673-8. <LINK TO ABSTRACT>

Hailey D et al. Recommendations and Supporting Evidence in Guidelines for Referral of Patients to Sleep Laboratories. *Sleep Medicine Reviews* (2006);10:287-99. <LINK TO ABSTRACT>

Hailey D and Tran K. Quality and Relevance of Evidence in Support of Guideline Recommendations for Sleep Laboratory Investigations. *International Journal of Technology Assessment in Health Care* (2005);21(4):459-63. <LINK TO ABSTRACT>

Institute for Clinical Systems Improvement (ICSI). *Health Care Guideline: Diagnosis and Treatment of Obstructive Sleep Apnea in Adults.* Bloomington, MN. (2007). <LINK TO GUIDELINE>

Kushida CA et al. Practice Parameters for the Indications for Polysomnography and Related Procedures: An Update for 2005. *Sleep* (2005);28(4):499-521. <LINK TO GUIDELINE SUMMARY>

Patil SP et al. Adult Obstructive Sleep Apnea: Pathophysiology and Diagnosis. *Chest* (2007);132:325-37. <LINK TO ABSTRACT>

Scottish Intercollegiate Guidelines Network (SIGN). *Management of Obstructive Sleep Apnoea/Hypopnoea Syndrome in Adults: A National Clinical Guideline.* Edinburgh, Scotland. (2003). <LINK TO GUIDELINE>

Table 1: Evidence Consulted

Organization/Title/Year Method to Analyze Evidence	Scope	Objectives	Methods to Make Recommendations/Conclusions
American Academy of Sleep Medicine 2005 (Medical Specialty Society) **Systematic Review**	Diagnosis	To reissue, modify, and, if necessary, replace recommendations for indications for polysomnography and related procedures based on the scientific literature published since 1997.	Expert Consensus
American Academy of Sleep Medicine, American Thoracic Society, and American College of Chest Physicians 2003 (Medical Specialty Societies) **Systematic Review**	Diagnosis	To systematically evaluate the data on the use of portable monitoring devices and develop practice parameters.	Expert Consensus
Canadian Coordinating Office for Health Technology Assessment 2005 (Government Agency) **Systematic Review**	Diagnosis	To identify recommendations for the investigation of individuals in sleep laboratories, as made in guidelines prepared by professional bodies; and to review the nature, quality and relevance of the evidence cited in support of these recommendations.	Expert Consensus
Canadian Sleep Society/Canadian Thoracic Society 1996 (Medical Specialty Societies) **Literature Review**	Diagnosis	To develop standards for polysomnography in Canada in order to assist in the uniform provision of diagnostic and therapeutic services related to sleep disorders.	Expert Consensus
Institute for Clinical Systems Improvement (ICSI) 2007 (Private Non-Profit Organization) **Systematic Review**	Diagnosis Treatment	To assist clinicians by providing an analytical framework for the evaluation and treatment of obstructive sleep apnea in adults.	Expert Consensus
Scottish Intercollegiate Guidelines Network 2003 **Systematic Review**	Diagnosis Evaluation Treatment	To produce recommendations which can be used to aid patients, general practitioners (GPs), secondary care physicians, and surgeons to recognize the symptoms of obstructive sleep apnoea/hypopnoea syndrome, to prioritise referral requests, to understand how sufferers may be investigated and which treatment modalities are currently available.	Expert Consensus

APPENDIX A:
Blue Cross and Blue Shield of MN Authorization Criteria – Pediatric Sleep Studies/Polysomnograms

Accessed 2/25/08 at:
<http://www.bluecrossmn.com/public/providers/htdocs/medical_policy_statement.html>

PEDIATRIC SLEEP STUDIES/POLYSOMNOGRAMS

Description: Both a pediatric **sleep** study and polysomnogram are attended multi-channel recordings of a number of patient physiological parameters which occur during **sleep** (i.e. chest/abdominal effort, EKG, pH, O2 saturation). By adding additional recording channels, a polysomnogram is different in that it is able to map the physiological **sleep** abnormalities to the stage of **sleep** in which they occur.

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Policy: A pediatric **sleep** study/polysomnography is considered **ACCEPTED MEDICAL PRACTICE** in the following situations:

1. A child with the following symptoms may be eligible if symptoms are accompanied by snoring and if all other causative factors have been ruled out:
   - daytime hypersomnolence
   - failure to thrive
   - cor pulmonale
   - polycythemia
2. In children with Down's or Pierre Robin Syndrome or any craniofacial abnormalities resulting in mid or lower facial disorders having symptoms of obstructive **sleep** apnea
3. In children with laryngomalacia (small oropharynx)
4. In obese children or adolescents who also have hypercapnia, chronic snoring, daytime hypersomnolence, polycythemia, or cor pulmonale
5. In children with Sickle Cell disease with signs and symptoms of obstructive **sleep** apnea
6. In children with neuromuscular disease who also have signs and symptoms of snoring and swallowing abnormalities
7. In children with tracheostomies prior to removal of the tracheostomy tube
8. In children with seizures

Unattended home **sleep** studies are considered **INVESTIGATIVE.**

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Coverage: **Prior authorization: No.** This policy applies to individuals up to 16 years of age.

Coding: CPT codes 95805, 95806, 95807, 95808, 95810, 95811

Medical Policy Committee Review:
Developed February 14, 1996
Code Update May 9, 1997 Revised February 14, 2001
Revised November 13, 2002
Revised May 28, 2003 (coverage section)
Reviewed October 13, 2004
Reviewed September 14, 2005
Reviewed October 11, 2006
Reviewed November 14, 2007

Medical Policy Subcommittee Review:
Reviewed October 1, 1998
Reviewed August 11, 1999

HSAC Evidence Summary

Sleep Studies for Adults

Reviewed December 13, 2000

Cross Reference:

Adult **Sleep** Study/Polysomnography VIII-1

Apnea Appliances VII-26

Palatoplasty, Uvulopalatopharyngoplasty IV-7

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APPENDIX A:
HSAC Process for Summarizing Evidence

Background: HSAC, in conjunction with the DHS Medical Director, is charged with advising the Department on clinical issues to inform decision-making on coverage and benefit policy. Where applicable, DHS produces summaries of existing clinical evidence to ensure that these decisions are based on the most up-to-date and reliable clinical evidence as well as the expertise of the Council's members.

Sources: The key sources used to gather evidence is gathered are summarized below:

- **Medicaid-Specific Collaborations:** Two key organizational collaborations provide a starting point for the evaluation of topics, helping to frame clinical questions and serving as channels for consultation with other states' programs in making evidence-based coverage decisions.
    - Medicaid Evidence-Based Decisions (MED) Project – A collaboration of state Medicaid programs housed at the Center for Evidence-Based Policy at Oregon Health & Science University. MED Project creates reports and recommendations based upon clinical evidence, provides staff support and facilitates knowledge sharing between states.
    - AHRQ/AcademyHealth Medicaid Medical Directors' Learning Network – A forum for the sharing of research and experience among medical directors in state Medicaid programs across the country.
- **Keyword Searches:** Topical keyword searches are then performed, searching for clinical guidelines and relevant peer-reviewed articles using the following sources:
    - AHRQ National Guidelines Clearinghouse – A clearinghouse of recommended guidelines from medical specialty societies, private non-profit organizations, and evidence-based practice centers.
    - The Cochrane Library – An international database of clinical practice guidelines. (Access to full-text resources is somewhat limited currently.)
    - PubMed and Medline – Medical/health sciences bibliographic databases.
- **Resources Accessed Directly:** Other sources are routinely accessed directly in search of clinical guidelines and peer-reviewed articles:
    - AHRQ Evidence-Based Program – A repository of rigorous clinical reports from grant-funded evidence-based practice centers across the U.S. and Canada.
    - Institute for Clinical Systems Improvement (ICSI) – A locally-based, nationally recognized collaboration of health care organizations that identifies best clinical practices and facilitates their implementation.
    - Technology Assessments:
        - Blue Cross and Blue Shield Association Technology Evaluation Center
        - ECRI Institute (Access provided through the MED Project)
        - ICSI

Process: After information is gathered and reviewed, sources are chosen with a preference for clinical practice guidelines (from professional organizations or independent non-profits), meta-analyses and systematic reviews, supplemented by quality peer-reviewed primary articles. Preference is also given to the most up-to-date evidence available. Summary documents are then created, providing brief background and context for the clinical issue, the amount, quality, and reliability of the evidence, and proposed action to be taken based upon that evidence. These documents are reviewed internally among DHS staff (including physicians) before coming before HSAC. HSAC uses these summary documents as a starting point for discussion around the issue in question, drawing upon their assessment of the evidence and their clinical expertise to advise DHS.

Spinal Cord Stimulation for Chronic Pain

Health Services Advisory Council

Evidence Summary

August 5, 2008

Minnesota Department of **Human Services**

Background/Context

Neuropathic pain (pain caused by damage or dysfunction of the nervous system) has a reported prevalence of anywhere from 1.5% to 8% in the primary care population .[1] One mode of treatment for the management of chronic pain is spinal cord stimulation, in which electrodes are implanted in the epidural space and a generated electrical pulse provides a paresthesia sensation that alters the patient's perception of pain. Patients generally undergo a trial period of stimulation to gauge treatment effect prior to full implantation. While the precise mechanisms of pain relief from spinal cord stimulation remain uncertain,[2] the technology has been in use since the late 1960s and has been incorporated into some clinical practice guidelines for pain management.[3]

Two of the most common indications for spinal cord stimulation under the category of chronic pain are failed back surgery syndrome (FBSS; chronic pain following lumbar spine surgery) and complex regional pain syndrome (CRPS; formerly known as reflex sympathetic dystrophy). FBSS is particularly prevalent in the United States given the high per capita rate of back surgery compared with other developed nations and the variation in long term post-surgical outcomes. Although both syndromes are seen frequently in specialized pain treatment settings, "treatments are varied, scientifically unproven, and often costly."[4]

As part of a broader evidence review on chronic low back pain interventions, the Medicaid Evidence-based Decisions (MED) Project at Oregon Health & Science University evaluated the evidence related to spinal cord stimulation for FBSS and CRPS. The MED Project review forms the basis of the summary that follows, and each of the sources identified in the MED review is cited individually herein. While not an enormous cost-driver in the fee-for-service Minnesota Health Care Programs (professional fees totaled nearly $600,000 in calendar year 2007), spending on spinal cord stimulation procedures increased over 140% from calendar year 2003 through 2007, with many low back pain and non-specific diagnosis codes appearing on claims. The increase in the rate of unsuccessful back surgeries nationwide and the relatively high unit cost of spinal cord stimulation (initial costs for the implanted components top $10,000 in the U.S.)[5] make it worthwhile to examine the evidence of its efficacy in treating chronic pain.

Summary of Evidence

The evidence reviewed includes two systematic reviews assessing spinal cord stimulation for chronic pain conditions, and a third review examining its cost effectiveness. The MED Project also identified two relevant clinical trials published since the systematic reviews.

The findings from the two high-quality systematic reviews were largely based on the same pair randomized controlled trials (RCT) – one addressing FBSS and another addressing CRPS. [6] Their conclusions are summarized below.

- A Cochrane review was published in 2004 which looked at spinal cord stimulation vs. surgery for FBSS, as well as spinal cord stimulation plus physical therapy vs. physical therapy alone for CRPS. The authors limited the review to controlled clinical trials, yielding only two studies that met the inclusion criteria. Given the scarcity of high-quality studies, the authors concluded that there was insufficient evidence to determine the benefits and harms of spinal cord stimulation.

- Another systematic review by Turner et al., published in the journal *Pain* in 2004 examined the effectiveness and complications of spinal cord stimulation for FBSS and CRPS. The Turner et al. review included one RCT (also included in the Cochrane review), as well as 22 lower-quality studies of mixed design. The authors concluded that there was moderate evidence that spinal cord stimulation plus physical therapy was more effective than physical therapy alone in relieving pain from CRPS at 6 and 12-month follow-ups, characterizing the average pain relieving effect as "modest". The authors further pointed out the 34% rate of adverse occurrences among patients receiving stimulators; although few were life-threatening, many necessitated additional surgeries.

A third review focused on the cost-effectiveness of spinal cord stimulation in the treatment of chronic pain.

- The Taylor et al. review was published in the *Journal of Pain and Symptom Management* in 2004. The review identified a single full economic evaluation that compared both the costs and outcomes of spinal cord stimulation with physical therapy for CRPS to physical therapy alone, reporting a cost of $22,500 per quality-adjusted life year (QALY) at one-year follow-up. Taylor et al. concluded that spinal cord stimulation is economically favorable compared with other therapies, while acknowledging the poor quality of the evidence base and the lack of well-designed studies addressing each of the indications for spinal cord stimulation.

Two additional RCTs have been published in the meantime. A trial by Kumar et al., published in 2007 and considered to be of moderate quality by MED Project staff, compared spinal cord stimulation with conventional medical management to medical management alone in 100 patients. The authors reported that the spinal cord stimulation group had significantly greater pain relief, quality of life, functional capacity, and treatment satisfaction. The second RCT, by North et al., was published in 2005. This study reported benefits of spinal cord stimulation for FBSS compared to reoperation, but is considered to be of low quality due to small sample size, use of self-reported outcome measures, and high rate of cross-over.[7]

Conclusions

There is little high-quality evidence from which to draw conclusions regarding the effectiveness of spinal cord stimulation for chronic pain. Although one recent trial reported positive outcomes, systematic reviews of the body of literature have offered insufficient evidence, and much of what has been published has been of low quality. Consistently high rates of reported complications must be taken into consideration when assessing the proper place of this therapy in managing chronic pain, as well as the apparently diminishing pain-relieving effect of spinal cord stimulation in studies with longer follow-up. In the best-known trials, patients in the control groups had previously failed to respond to the comparison treatment and were not given sham treatment, increasing the likelihood of a strong "placebo effect" in patients receiving the technological intervention.

An evidence-based coverage policy would restrict coverage to carefully selected patients to maximize the likelihood of positive outcomes. A proposed set of authorization criteria follows.

DHS will authorize spinal cord stimulation to treat irreversible chronic neuropathic pain that is refractory to other treatment modalities. The use of spinal cord stimulation for other indications will be reviewed on a case-by-case basis and approved as medically necessary. For chronic pain (including failed back surgery syndrome and chronic regional pain syndrome), all of the following criteria must be met for approval:

1) The treatment is used after other patient-appropriate therapies have been tried and proven ineffective, including but not limited to pharmacological management, injection therapies, physical therapy, and surgery and/or psychological treatment if indicated.

   DOCUMENTATION REQUIRED: Written description of prior therapies attempted and patient's response.

2) The patient has been evaluated by a multidisciplinary pain management team which offers multiple coordinated treatment modalities at a single site (such as an integrated care delivery team). Teams must incorporate mental health and chemical dependency screenings for all patients and, where appropriate, evaluations by licensed mental health professionals.

   DOCUMENTATION REQUIRED: Supporting documentation of the patient's evaluation by a multidisciplinary team and a list of the providers that compose the team.

3) The patient and the referring physican have participated in a shared decision making process in which evidence is evaluated, treatment options are discussed, and risk and benefit are weighed. This shared decision making process must be informed by a patient decision aid, to be developed by the implanting physician and made available to the patient and referring physician. The patient decision aid must, at a minimum:[8]

   - Provide information about options in sufficient detail for decision making.
   - Present probabilities of outcomes in an unbiased and understandable way.
   - Include methods for clarifying and expressing patients' values.
   - Include structured guidance in deliberation and communication.
   - Present information in a balanced manner.
   - Use up to date scientific evidence that is cited in a reference section or technical document.
   - Disclose conflicts of interest.
   - Use plain language.

   DOCUMENTATION REQUIRED: A copy of the patient decision aid developed by the implanting physician/practice and used in the shared decision making process (to be kept on file with the medical

reviewer); and documentation of the occurrence of the shared decision making process, including the date and referring physician.

4) A trial insertion of a minimum of three days (preceding permanent implantation) leads to pain relief and improvement in function. (Authorization requests should be submitted prior to the temporary insertion – if the trial period is successful, no additional authorization is needed.)

Evidence Consulted

Kumar, K et al. Spinal Cord Stimulation versus Conventional Medical Management for Neuropathic Pain: A Multicentre Randomised Controlled Trial in Patients with Failed Back Surgery Syndrome. *Pain* (2007); 132: 179-188.

WEB LINK TO ABSTRACT

Mailis-Gagnon, A et al. Spinal Cord Stimulation for Chronic Pain. *Cochrane Database of Systematic Reviews* (2004); 3: CD003783.

WEB LINK TO ABSTRACT

North, RB et al. Spinal Cord Stimulation versus Repeated Lumbosacral Spine Surgery for Chronic Pain: A Randomized, Controlled Trial. *Neurosurgery* (2005); 56(1): 98-107.

WEB LINK TO ABSTRACT

Oregon Health & Science University (OHSU) Center for Evidence-Based Policy. *Rapid Review: Interventions for Chronic Low Back Pain*. Portland, OR. (2008).

Taylor, RS et al. The Cost Effectiveness of Spinal Cord Stimulation in the Treatment of Pain: A Systematic Review of the Literature. *Journal of Pain and Symptom Management* (2004); 27(4): 370-378.

WEB LINK TO ABSTRACT

Turner, JA et al. Spinal Cord Stimulation for Patients for Failed Back Surgery Syndrome or Complex Regional Pain Syndrome: A Systematic Review of Effectiveness and Complications. *Pain* (2004); 108: 137-147.

WEB LINK TO ABSTRACT

References

[1] Kumar, K et al. Spinal Cord Stimulation versus Conventional Medical Management for Neuropathic Pain: A Multicentre Randomised Controlled Trial in Patients with Failed Back Surgery Syndrome. *Pain* (2007); 132: 179-188.

[2] Turner, JA et al. Spinal Cord Stimulation: Stimulating Questions. *Pain* (2007); 132: 10-11.

[3] Taylor, RS et al. The Cost Effectiveness of Spinal Cord Stimulation in the Treatment of Pain: A Systematic Review of the Literature. *Journal of Pain and Symptom Management* (2004); 27(4): 370-378.

[4] Turner, JA et al. Spinal Cord Stimulation for Patients for Failed Back Surgery Syndrome or Complex Regional Pain Syndrome: A Systematic Review of Effectiveness and Complications. *Pain* (2004); 108: 137-147.

[5] Taylor et al.

[6] Kemler, MA et al. Spinal Cord Stimulation in Patients with Chronic Reflex Sympathetic Dystrophy. *New England Journal of Medicine* (2000); 343(9): 618-624

and

North, RB and Kidd, DH. Spinal Cord Stimulation versus Reoperation for Failed Back Surgery Syndrome: A Prospective, Randomized Study Design. *Acta Neurochirurgica Suppl.* (1995); 64:106-108.

[7] Turner, JA et al. Spinal Cord Stimulation: Stimulating Questions. *Pain* (2007); 132: 10-11.

[8] International Patient Decision Aid Standards (IPDAS) Collaboration

Table 1: Evidence Consulted

Organization/Title/Year **Method to Analyze Evidence**	**Scope**	**Objectives**	**Methods to Make Recommendations/ Conclusions**
Kumar et al. 2007 **Journal Article**	- Evaluation - Treatment	To test the hypothesis that spinal cord stimulation in addition to conventional medical management is more effective in failed back surgery syndrome patients than conventional medical management alone.	Multi-center Randomized, Controlled Trial (RCT)
Mailis-Gagnon, A et al. 2004 *(Cochrane Database of Systematic Reviews)*	- Evaluation - Treatment	To assess the efficacy and effectiveness of spinal cord stimulation in relieving certain kinds of pain, as well as the complications and adverse effects of this procedure.	Systematic Review
North, RB et al. 2005 *(Journal Article)*	- Evaluation - Treatment	To test the hypothesis that spinal cord stimulation is more likely than reoperation to result in a successful outcome by standard measures of pain relief and treatment outcome, including subsequent use of health care resources.	Randomized, Controlled Trial (RCT)
OHSU Center for Evidence-Based Policy 2008 *(Membership-Based Medicaid Research Organization)*	- Diagnosis - Evaluation - Treatment	To conduct an overview of the existing research evidence on the effectiveness and safety of a range of interventions for the treatment of chronic low back pain of non-malignant origin.	Systematic Review
Taylor, RS et al. 2004	- Treatment	To identify and evaluate studies of the cost-	Systematic

APPENDIX A: Proposed Codes

CPT	Description
61885	Connection of the electrode to an implanted programmable pulse generator in the infraclavicular area
63650	Percutaneous implantation of neurostimulator electrode array, epidural
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
63660	Revision or removal of spinal neurostimulator electrode array(s) or plate/paddle(s)
63685	Insertion or replacement of spinal stimulator pulse generator or receiver, direct or inductive coupling
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver (Do not report 63685 in conjunction with 63688 for the same pulse generator or receiver)
95970	Electronic analysis of implanted neurostimulator pulse generator system; simple or complex brain, spinal cord, or peripheral neurostimulator pulse generator/transmitter, without reprogramming
95971	Simple spinal cord, or peripheral neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
95972	Complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour
95973	Complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter with intraoperative or subsequent programming, each additional 30 minutes after first hour (list separately in addition to code for primary procedure) (Use 95973 in conjunction with 95972)
HCPCS	
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable pain neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
L8689	External recharging system for implanted neurostimulator, replacement only
ICD-9 Proc	
03.93	Implantation or replacement of spinal neurostimulator lead(s)
03.94	Removal of neurostimulator leads
86.94	Insertion or replacement of single array neurostimulator pulse generator, not specified as rechargeable
86.95	Insertion or replacement of dual array neurostimulator pulse generator, not specified as rechargeable
86.96	Insertion or replacement of other neurostimulator pulse generator
86.97	Insertion or replacement or single array rechargeable neurostimulator pulse generator
86.98	Insertion or replacement of dual array rechargeable neurostimulator pulse generator
V53.02	Fitting and adjustment of neuropacemaker (brain, peripheral nerve, spinal cord)

APPENDIX B:
HSAC Process for Summarizing Evidence

Background: HSAC, in conjunction with the DHS Medical Director, is charged with advising the Department on clinical issues to inform decision-making on coverage and benefit policy. Where applicable, DHS produces summaries of existing clinical evidence to ensure that these decisions are based on the most up-to-date and reliable clinical evidence as well as the expertise of the Council's members.

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    - AHRQ/AcademyHealth Medicaid Medical Directors' Learning Network – A forum for the sharing of research and experience among medical directors in state Medicaid programs across the country.

- **Keyword Searches:** Topical keyword searches are then performed, searching for clinical guidelines and relevant peer-reviewed articles using the following sources:
    - AHRQ National Guidelines Clearinghouse – A clearinghouse of recommended guidelines from medical specialty societies, private non-profit organizations, and evidence-based practice centers.
    - The Cochrane Library – An international database of clinical practice guidelines. (Access to full-text resources is somewhat limited currently.)
    - Medline (Full-Text Only) – The National Library of Medicine's bibliographic database and search engine.

- **Resources Accessed Directly:** Other sources are routinely accessed directly in search of clinical guidelines and peer-reviewed articles:
    - AHRQ Evidence-Based Program – A repository of rigorous clinical reports from grant-funded evidence-based practice centers across the U.S. and Canada.
    - Institute for Clinical Systems Improvement (ICSI) – A locally-based, nationally recognized collaboration of health care organizations that identifies best clinical practices and facilitates their implementation.
    - Journal Subscriptions:
        - New England Journal of Medicine
        - Health Affairs
    - Technology Assessments:
        - Blue Cross and Blue Shield Association Technology Evaluation Center
        - ECRI (Access provided through the MED Project)
        - ICSI

Process: After information is gathered and reviewed, sources are chosen with a preference for clinical practice guidelines (from professional organizations or independent non-profits), meta-analyses and systematic reviews, supplemented by quality peer-reviewed primary articles. Preference is also given to the most up-to-date evidence available. Summary documents are then created, providing brief background and context for the clinical issue, the amount, quality, and reliability of the evidence, and proposed action to be taken based upon that evidence. These documents are reviewed internally among DHS staff (including physicians) before coming before HSAC. HSAC uses these summary documents as a starting point for discussion around the issue in question, drawing upon their assessment of the evidence and their clinical expertise to advise DHS.

Spinal Cord Stimulation for Chronic Pain:

- **Complex Regional Pain Syndrome (CRPS)**
- **Failed Back Surgery Syndrome (FBSS)**

Health Services Advisory Council

Evidence Summary

May 13, 2010

Minnesota Department of **Human Services**

Abstract

In 2008, HSAC selected spinal cord stimulators as a topic as part of a broader evidence review on chronic low back pain interventions. Spinal cord stimulators (SCS) are used when patients have intractable back or radiating pain from either failed back surgery or complex regional pain syndromes.

The 2008 HSAC recommendations proposed limited coverage and included a provision to require a shared decision making process to promote informed, values-based patient decision making. The shared decision making was to be performed by the referring provider, a departure from the usual process of having the interventional provider discussing care options. This change in process was supported because the referring provider would be unlikely to have a conflict associated with performing the procedure

In 2009, in response to legislative request, HSAC performed a thorough evidence review of shared decision making. The report concluded that there was insufficient evidence regarding the effectiveness of shared decision making in clinical practice to justify making payment conditional on its use. As a result, HSAC decided to revisit its recommendations on spinal cord stimulators. The report was also revised to incorporate new research and reflected feedback from local and national SCS surgeons and non-interventionalists.

This revised report reflects newer evidence regarding the safety and effectiveness of SCS.

Background/Context

Neuropathic pain, arising as direct consequence of a lesion or disease affecting the somatosensory system (Geber C. et al, 2009) has an unknown prevalence. Some studies estimate the prevalence to be between 1.5 and 8% (Kumar et al, 2007). The diagnosis of neuropathic pain is problematic and there is no specific diagnostic tool to make a definitive diagnosis; therefore a grading system of definite, probably, or possible neuropathic pain has been recommended (Geber C et al, 2009). One mode of treatment for the management of chronic pain is spinal cord stimulation (SCS), in which electrodes are implanted in the epidural space and a generated electrical pulse provides paresthesia sensations that alters the patient's perception of pain (Turner et al, 2007a). Patients generally undergo a trial period of stimulation to gauge treatment effect prior to full implantation. While the precise mechanisms of pain relief from spinal cord stimulation remain uncertain (Turner et al, 2007), the technology has been in use since the late 1960s and has been incorporated into some clinical practice guidelines for pain management (Taylor et al, 2004).

Two of the most common indications for spinal cord stimulation under the category of chronic pain are failed back surgery syndrome (FBSS; chronic radicular pain following lumbar spine surgery) and complex regional pain syndrome 1 (CRPS -1; formerly known as reflex sympathetic dystrophy). FBSS is particularly prevalent in the United States given the high per capita rate of back surgery compared with other developed nations and the variation in long term post-surgical outcomes. Both syndromes are seen frequently in specialized pain treatment settings in the United States.

In calendar year 2008, over 300 fee-for-service (FFS) recipients received back surgery for a back pain diagnosis, at a cost of $3.8 million dollars. In this same year, 112 FFS recipients had spinal cord stimulator procedures, at a cost of $1.2 million dollars.

Although this was not a significant driver of overall costs for the Minnesota Health Care Programs (MHCP), the increase in the rate of unsuccessful back surgeries nationwide (Taylor et al, 2004) and the high cost of implant ($32,882 - $57,896) (Kumar et al, 2009) continue to make it worthwhile to examine the evidence of its efficacy in treating chronic pain. The Kumar study estimates the annual maintenance cost of an uncomplicated case to be $5,071 in US Medicare and $7,277 in US BlueCross Blue Shield (BCBS). The mean cost of a complication was estimated to be $9,649 (range $381 - $28,495) for Medicare and $21,390 (range $573 - $54,547) for BCBS.

This document was originally written in 2008. In order to update this document, an analysis of more recent literature has been performed by DHS staff.

Summary of Evidence

There are four main series of clinical trials that are reviewed in this report. The Kemlar et al studies (2000, 2001, 2002, and 2008) focused on treatment for complex regional pain syndrome (CPRS), comparing spinal cord stimulation (SCS) and physical therapy (PT) to PT alone. The other three series of trials focused on treatment for failed back surgery syndrome (FBSS). The Kumar et al studies (2007, 2008), known as the PROCESS trial, compared SCS with conventional medical management (CMM). The North et al studies (1994, 1995, 2005, 2007) compared SCS with re-operation. The Turner study (2010) compared SCS, evaluation at a multidisciplinary pain clinic, and usual care. An outline of the studies is shown in Table 1 of Appendix A. Figures 1-4 in Appendix A provide diagrammatic representations of the study designs.

Several systematic reviews have been published that relate to these studies. An outline of the systematic reviews is shown in Table 2 of Appendix A. In addition, a number of relevant clinical guidelines have been published; these are outlined in Table 3 of Appendix A. The clinical trials and systematic reviews are described in more detail, below.

Clinical Trials

Kemlar et al, 2000, 2001
Kemlar et al (2000, 2001) enrolled 54 patients with CRPS who had previously failed to respond to standard therapy (6 months of physical therapy, sympathetic blockade, transcutaneous electrical nerve stimulation (TENS), and pain medication). Thirty-six patients were randomized to SCS and PT, 18 were randomized to PT alone. Twelve patients failed to respond to the test simulation of SCS and were excluded. The remaining patients (24 + 18) were followed for 6 months. According to the authors, there was limited evidence that SCS improved pain (but not function). Additionally, there was no long-term effect on detection and pain thresholds for pressure, warmth, and cold.

Kemlar et al, 2002
At 12 months, Kemlar et al (2002) published a follow up report that included an economic analysis. The authors concluded that there was moderate evidence that SCS plus PT was more effective than physical therapy alone at relieving pain from CRPS at 6 and 12 months. From baseline to 1 year, pain intensity decreased from an average of 7.1 to 4.4 in the group randomized to PT plus SCS, and increased from 6.7 to 7.1 in the group randomized to PT only ($P < 0.001$). The economic analysis measured costs for one year (in the Netherlands) and projected to death. The authors stated that although the costs associated with each patient randomized to SCS plus PT exceeded those of PT alone at 12 months ($10,197 and $5,971, respectively), this difference was projected to be reversed over a lifetime. See Figure 1 in Appendix A for a diagram of the study design.

Kemlar et al, 2008
Kemlar et al (2008) published a 5-year follow-up of their RCT on spinal cord surgery and physical therapy versus PT alone for complex regional pain syndrome Type I. The study found that the pain-alleviating effect of SCS in patients with chronic CRPS-I diminished over time, and was no longer significant at 3 years of follow-up. Overall, during the 5 years of treatment, 10 of 24 patients underwent reoperation as a result of 29 complications. Most (21 of 29) of the complications occurred during the first 2 years.

These studies were conducted in the Netherlands, and were supported by a grant from the Dutch Health Insurance Council. None of the authors reported a financial interest in the subject under discussion.

Kumar et al, 2007 (PROCESS)
The PROCESS trial (Prospective Randomized Controlled Multi-center Trial of the Effectiveness of Spinal Cord Stimulation) randomized 100 patients in a total of 12 centers in Europe, Canada, Australia, and Israel to receive SCS plus conventional medical management (CMM) or CMM alone (Kumar, 2007). The trial did not include any sites in the United States. Patients in this trial had FBSS, with leg pain greater than back pain. The authors reported that the SCS group had significantly greater pain relief, quality of life, self-reported function, and treatment satisfaction at 6 months.

According to an editorial review (Turner et al, 2007a), the design (Kumar, 2007) does not allow for conclusions regarding the extent to which patient improvement with SCS is due to the placebo effect. Patients in the SCS group received a new "high-tech" therapy, compared with patients in the control group receiving a treatment that had already proven ineffective. According to this review, a study with a sham control would be necessary to determine the magnitude of any "placebo" effects. However, given that a sham surgical procedure could jeopardize patient safety, it is unlikely that sham SCS trials will be conducted.

Kumar et al, 2008
After 6 months, patients could request crossover to the alternative treatment. The 24 month follow-up to this study was published by Kumar et al in 2008. Results were presented for the 42 (of 52) patients randomized to SCS in the PROCESS trial who continued to use SCS at 24 months. The 10 patients who failed to respond to SCS were excluded from the analysis. The 11 patients who remained in the CMM group were not studied. The authors deemed this to be too small a number to undertake a companion analysis. Compared with baseline, the 42 patients reported significantly improved leg pain, quality of life, and function. There was no significant change from baseline in back pain intensity. A total of 34 complications occurred, with 45% of patients of the 42 patients experiencing more than one adverse event. A device-related surgical revision was required by 31% of patients. The study does compare both intention-to-treat (37% and 2%) and as-treated (47% and 7%) success for SCS and CMM, but these results include significant crossover data. As results were not given for the patients who remained on conventional medical management versus the patients who remained on SCS, it is unknown how SCS compares with CMM. See Figure 2 in Appendix A for a diagram of the study design.

These studies were funded by, and data were collected and analyzed by, the manufacturer of the SCS device. Additionally, two authors have been paid consultants for the device manufacturer.

North et al, 1994, 1995
North et al published a two-part study in 1994 and 1995 that compared SCS with reoperation for patients with FBSS. The primary outcome of both studies was the frequency of crossover to the alternate procedure at 6 months. Results for the first 27 patients showed more patient preference for crossover to SCS.

North et al, 2005
North et al published in 2005 study that reported benefits of spinal cord stimulation for FBSS compared to reoperation. However, 39% of eligible patients did not participate in the study because they preferred reoperation. A number of eligible patients were not treated and not followed up for assessment because they had worker's compensation insurance, and that insurance did not authorize treatment. Thus, study results may not be generalizable to workers' compensation recipients. In this study, 60 patients were randomized, 50 of those received SCS or reoperation, and 45 were assessed at long-term follow-up. This study has a small sample size, use of self-reported outcome measures, and high rate of cross-over. See Figure 3 in Appendix A for a diagram of the study design.

North et al, 2007
In 2007, North et al published an article that reported economic data on 40 of the first 42 patients randomized in the North (2005) RCT of SCS versus reoperation for FBSS. In this study, 21 patients were randomized to SCS and one refused to have costs data collected, and another died, so 19 patients randomized to SCS were analyzed. Of the 19 patients randomized to SCS, 5 (26%) crossed over to reoperation. Most (13 of 21) patients randomized to reoperation crossed over to SCS. The costs were reported in the article in 1991-1995 US dollars. The follow-up period varied from 1.6 to 4.7 years, and costs incurred outside the clinical setting of the study were not captured. According to the study, the cost efficacy of SCS as a sole therapy was found to be more than twice that of reoperation as a sole therapy. Because of the small study numbers, small absolute differences, wide confidence intervals, and high level of crossover in this study, any results should be interpreted with caution.

The study received industry funding.

Turner et al, 2010
Turner et al published a prospective, population-based cohort study in 2010 that evaluated outcomes of worker's compensation recipients with FBSS who received at least a trial of SCS (SCS n = 51) versus those who were 1) evaluated at a multidisciplinary pain clinic and did not receive SCS (pain clinic n = 39), or 2) received neither pain clinic evaluation nor SCS (usual care n = 68). The three groups did not differ on the primary outcome (the composite index of pain, function, and opioid medication use) and few patients achieved success by this criterion at any time point. At 6 months, SCS patients were more likely than pain clinic patients to report improvement in leg pain, but were also more likely to report daily opioid medication use. At 12 and 24 months, all 3 groups did not differ in terms of pain improvement, function, or work status. Patients with high expectations of SCS effectiveness had almost four times the odds of a successful trial, consistent with the possibility that expectations played a role. According to the authors, differences in study design, research subject population and delivery of care may explain why these results are more disappointing than those of previous RCTs. The authors note that the issues associated with involvement in a workers' compensation system may have a stronger influence than pain therapy on patient outcomes.

This study was funded by the Washington State Department of Labor and Industry.

According to a review of the Turner study (2009) by Wasan (2009), although the authors attempted to correct for baseline differences, the statistical power to separate the unique variance in treatment response to SCS is limited. The review questioned the use of opioids in the composite primary outcome, as SCS is generally more effective for leg pain than back pain, and patients might be expected to have significant back pain for which they might still require opioids. The review also commented that only 25% of the SCS group had psychological evaluations beforehand, making it possible that poor patient selection was, in part, responsible for the poor results. In addition, the review notes that patients with a workers' compensation claim have been demonstrated to have poor outcomes with pain treatment, whether it is physical rehabilitation or spine surgery.

Systematic Reviews

Cochrane, 2004, 2009 (CRPS, FBSS)
A Cochrane review, published in 2004, looked at spinal cord stimulation vs. surgery for FBSS, as well as spinal cord stimulation plus physical therapy vs. physical therapy alone for CRPS. The authors limited the review to controlled clinical trials, yielding only two studies with a combined total of 81 patients that met the inclusion criteria. (Kemler 2000, 2001, 2002, and North 1994, 1995) Given the scarcity of high-quality studies, the authors concluded that there was insufficient evidence to

determine the benefits and harms of spinal cord stimulation. A 2009 reprint of this SR did not incorporate any new RCT evidence in the analysis.

Taylor et al, 2004 (CRPS)
Taylor et al. published a review in 2004 that considered the use of SCS across 5 indications, including FBSS (6 studies) and CRPS (1 study). Only the cost utility analysis (Kemler and Furnee 2002) was judged to be a full economic evaluation. According to the review, although the costs associated with each patient randomized to SCS plus physical therapy exceeded those of physical therapy alone at 12 months ($10,197 and $5,971, respectively), this difference would be reversed over a lifetime.

The study was supported by unrestricted funding by industry. As the study was conducted in the Netherlands ten years ago, costs may not be relevant to costs today in the US. Given that the extrapolated lifetime results are highly dependent on assumptions of projected costs that are based on one year of data collection, these conclusions are to be interpreted with caution.

Taylor et al, 2006 (CRPS)
Taylor et al published a systematic review on CRPS in 2006, but this economic analysis is paired with FBSS in another 2006 publication. According the authors, SCS appears to be an effective therapy in the management of patients with CRPS-1 (Level A evidence) and CRPS-2 (Level D evidence). Moreover, there is evidence to demonstrate that SCS is a cost-effective treatment for CRPS-1.

The study was supported by unrestricted funding by industry.

Taylor et al, 2006a (CRPS, FBSS)
Taylor published another economic evaluation in 2006, which reviewed the Kemlar RCT (Kemlar and Furnee, 2002), 25 case series studies, and one cost effectiveness study for CRPS. It also reviewed 1 RCT (North et al, 2005), 1 cohort study, 72 case series, and 4 cost studies for FBSS. According to the authors, the results support the use of SCS in patients with refractory neuropathic back and leg pain/FBSS (B) and CRPS-1 (A) -2(D).

Funding sources are not noted.

Turner et al, 2004 (CRPS, FBSS)
Turner et al. published a systematic review in the journal *Pain* in 2004. It examined the effectiveness and complications of spinal cord stimulation for FBSS and CRPS. This review of effectiveness included one RCT (Kemlar et al, 2000) as well as 6 case studies of much lower methodological quality. According to the SR, because the Kemler RCT was not blinded and because surgical techniques may have powerful non-specific (placebo) effects, the extent to which pain relief is due to the specific effects of SCS versus the placebo effects is unknown. The SR concluded that the literature on FBSS and CRPS remains inadequate to make definitive statements about efficacy in reducing physical disability, work disability, and medical consumption, and the strongest evidence suggests no benefits of SCS in improving functioning status of patients with CRPS-1.

The SR also analyzed 18 articles that reported sufficient information to calculate complication rates, and found that a weighted average of 34% of patients (range 0% to 81%) who received a stimulator had one or more undesirable outcomes during the study follow-up period. Although few of these complications were life-threatening, other adverse events were frequent.

The review received no industry funding, but was funded by the Medical Aid Fund of the Washington State Department of Labor and Industries. One of the three authors has received research grant support from, and has served as a lecturer and consultant, for industry.

Bala et al, 2008 (FBSS)
A systematic review of the cost-effectiveness of SCS for people with FBSS was published in 2008 (Bala et al, 2008). According to this review, the studies showed that SCS is effective in the treatment of FBSS in terms of pain reduction. Additionally, improvements were found in quality of life and function. The review also concluded that SCS was both more effective and less costly in the long term, but that there was an initial high cost associated with device implantation and maintenance.

An editorial by Chou (2008) found that these conclusions seemed to overstate the case for SCS. The studies used by this SR evaluated patients with persistent or recurrent radicular pain after back surgery; results are not applicable to FBSS associated with nonradicular pain. According to Chou, the cost effectiveness results were overly optimistic, given methodological problems with the two source studies.

Simpson et al, 2009 (CRPS, FBSS)
The 2009 Health Technology Assessment from the National Health Service of Great Britain reviewed the PROCESS trial and North trials for FBSS. According to this review, evidence suggests that SCS was more successful than CMM or reoperation in terms of pain relief. SCS resulted in more reduction in use of opiates than reoperation. SCS was more effective than CMM in improving functional ability and Health Related Quality of Life (HRQoL). There was no difference between SCS and reoperation in pain related to daily activities or neurological function. Medication use was similar for SCS and CMM groups. Employment status was not improved by SCS, CMM or reoperation. Regarding effectiveness in CRPS-I, this TA reviewed the Kemler trial and found that SCS was more effective than PT in reducing pain at 6 months and 2 years, but not at 5 years, and was more successful in terms of patients' global perceived effect (GPE)[1] of treatment

Frey et al, 2009
A 2009 SR by Frey et al reviewed the literature on SCS for FBSS. The SR concluded that there was level II-1 and level II-2 evidence to support long-term use of SCS for FBSS. The majority of included studies were observational.

Both primary and another author noted that they received industry funding.

[1] The global perceived effect (GPE) of treatment is a means of measuring self-perceived change in health status. Patients are asked to compare their current pain to that a previous time period.

Guidelines

Several guidelines have been published regarding the use of spinal cord stimulation for failed back surgery syndrome and complex regional pain syndrome.

- The American Pain Society (Chou, 2009) reviewed the evidence for non-surgical therapies for low back pain, and found that few of these interventions have been effective in placebo-controlled trials. The review also evaluated the Kumar (2007) and North (2005) studies on spinal cord stimulation. The authors found benefit to SCS for FBSS.
- The National Institute for Health and Clinical Excellence (NICE) developed a guidance in 2008 based on the TA by Simpson et al (2009). As there are no references included in the guidance, the recommendations are not admissible in this report.
- The European Federation of Neurological Societies published a guideline in 2007 (Crucco et al, 2007). The guideline developers found level B evidence for the effectiveness of SCS in failed back surgery syndrome (FBSS) and complex regional pain syndrome, type I (CRPS I).
- The Institute for Clinical Systems Improvement published a guideline in 2009 on assessment and management of chronic pain. According to the guideline, spinal cord stimulation for chronic low back pain resistant to adequate conservative therapy holds promise but has limited scientific evidence.
- The American Society of Interventional Pain Physicians published a guideline in 2007 (Boswell et al, 2007). This guideline recommends use of SCS for managing patients with FBSS. This guideline used the same interventions and patients groups as Cruccu et al (2007) but was of lower quality and not as current, according to IHE summary (2008).
- The Reflex Sympathetic Dystrophy Syndrome Association published a guideline in 2006 (RSDSA 2006). The guideline promotes a stepwise progression of treatment, from less invasive to more invasive (including SCS), for patients with persistent CRPS.
- The American Society of Anesthesiologists published a guideline in 2010 (ASA, 2010) on chronic pain management. It concluded that SCS be used for persistent CRPS following successful implantation of a trial implantation.

Conclusions and Proposed Authorization Criteria

Since this document was first written, more evidence has become available to guide policy. However, our review of the evidence identifies methodological challenges and suggests caution when interpreting results. Although some evidence suggests that SCS is more effective than conventional medical management or reoperation for pain relief of FBSS for the first six months to two years, long-term results do not appear to be better than alternatives. Similarly, based on a small study, SCS plus continued physical therapy appears to be more effective than physical therapy alone at improving pain, but not function, for up to two years, in patients with CRPS-1 who have not responded to physical therapy. Much of what has been published has been of low quality. Consistently high rates of reported complications must be taken into consideration when assessing the proper place of this therapy in managing chronic pain. In the best-known trials, patients in the control groups had previously failed to respond to the comparison treatment.

Coverage Criteria

An evidence-based coverage policy would restrict coverage to carefully selected patients to maximize the likelihood of positive outcomes. A proposed set of authorization criteria follows.

DHS will authorize spinal cord stimulation to treat intractable chronic neuropathic pain that is refractory to other treatment modalities. This pain should be primarily radicular, radiating to the leg. The use of spinal cord stimulation for other indications will be reviewed on a case-by-case basis and approved as medically necessary. For chronic pain (including failed back surgery syndrome and complex regional pain syndrome), all of the following criteria must be met for approval:

1) The treatment is used after all other patient-appropriate therapies have been tried and proven ineffective, including but not limited to pharmacological management, injection therapies, physical therapy, surgery and psychological treatment if indicated.

   DOCUMENTATION REQUIRED: Written description of prior therapies attempted and patient's response.

2) The patient has had a psychiatric diagnostic mental health and chemical health assessment by an appropriate provider (e.g., a psychologist or psychiatrist). The goals of this assessment are to rule out major psychiatric comorbidities or major substance abuse issues that would be strong predictors of poor outcomes and to select motivated patients who would be more likely to adhere to a follow-up plan.

   DOCUMENTATION REQUIRED: Supporting documentation of the patient's evaluation by an appropriate mental health professional (e.g. a psychologist or psychiatrist).

3) The following are recommendations for a robust informed consent discussion between physician and patient:
   - Provide information about treatment options and their probabilities for success in sufficient detail for decision making.
   - Present probabilities of outcomes in an unbiased and understandable way.
   - Include methods for clarifying and expressing patients' values.
   - Use plain language.

DOCUMENTATION REQUIRED: The patient and the implanting physician have participated in a robust informed consent process in which the following is documented:

- Treatment options are discussed.
- Risks and benefits are weighed.
- Patients are encouraged to approach the discussion from the context of their own values.
- Provider conflicts of interest (and extent of conflict of interest) are disclosed).
- Date(s) of discussion(s) are provided.

4) A trial insertion of a minimum of three days (preceding permanent implantation) leads to ≥ 50% pain relief and improvement in function. A validated pain measurement tool should be used. (Authorization requests should be submitted prior to the temporary insertion – if the trial period is successful, no additional authorization is needed.)

Proposed Codes

CPT

63650 - Percutaneous implantation of neurostimulator electrode array, epidural
63655 - Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
63661 – Removal of spinal neurostimulator electrode Percutaneous array(s), including fluoroscopy, when performed
63662 – Removal of spinal neurostimulator electrode plate/paddle placed via laminotomy or laminectomy, including fluoroscopy when performed
63663 – Revision, including replacement when performed, of spinal neurostimulator electrode Percutaneous array(s), including fluoroscopy when performed
63664 – Revision, including replacement when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy when performed
63685 - Insertion or replacement of spinal stimulator pulse generator or receiver, direct or inductive coupling
63688 - Revision or removal of implanted spinal neurostimulator pulse generator or receiver (Do not report 63685 in conjunction with 63688 for the same pulse generator or receiver)
95970 - Electronic analysis of implanted neurostimulator pulse generator system; simple or complex brain, spinal cord, or peripheral neurostimulator pulse generator/transmitter, without reprogramming
95972 - Complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour
95973 - Complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter with intraoperative or subsequent programming, each additional 30 minutes after first hour (list separately in addition to code for primary procedure) (Use 95973 in conjunction with 95972)

HCPCS

L8680 - Implantable neurostimulator electrode, each
L8681 - Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
L8682 - Implantable neurostimulator radiofrequency receiver
L8683 - Radiofrequency transmitter (external) for use with implantable pain neurostimulator radiofrequency receiver
L8685 - Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686 - Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687 - Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688 - Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
L8689 - External recharging system for implanted neurostimulator, replacement only

ICD-9 – CM Procedure Codes

03.93 - Implantation or replacement of spinal neurostimulator lead(s)
03.94 - Removal of neurostimulator leads
86.05 – Incision with removal of foreign body or device from skin and subcutaneous tissue
86.94 - Insertion or replacement of single array neurostimulator pulse generator, not specified as rechargeable
86.95 - Insertion or replacement of dual array neurostimulator pulse generator, not specified as rechargeable

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Appendix A: Evidence Consulted

Table 1: Clinical Trials

Number	Author*, Year and Type	Summary
1	**Kemler et al, 2000** RCT	There is limited evidence that SCS improves pain (but not function) in patients with CRPS-1.
2	**Kemler et al, 2001** RCT	The treatment has no long-term effect on detection and pain thresholds for pressure, warmth, or cold. The treatment seems to have only minimal influence on mechanical hyperalgesia.
3	**Kemler and Furnee, 2002** Economic Evaluation	There was moderate evidence that spinal cord stimulation plus physical therapy was more effective than physical therapy alone in relieving pain from CRPS at 6 and 12 months. Although the costs associated with each patient randomized to SCS plus physical therapy exceeded those of physical therapy alone at 12 months ($10,197 and $5,971, respectively), this difference was projected be reversed over a lifetime.
4	**Kemler et al, 2008** RCT	At 5 years post-treatment, SCS+PT produced results similar to those following PT for pain relief and all other measured variables.
5	**Kumar et al, 2007**** RCT	PROCESS Trial. SCS versus CMM for FBSS. SCS group had greater pain relief, quality of life, function and treatment satisfaction after 6 months.
6	**Kumar et al, 2008**** RCT-24 mo. Follow-up	PROCESS Trial. Compared with baseline, the SCS group reported significantly improved leg pain, quality of life, and function. As results were not given for the patients who remained on conventional medical management, it is unknown how SCS compares with CMM.
7	**North et al, 1994***	This is a two-part study. The first part gives results only for patient preference.
8	**North et al, 1995*** RCT	The second part of this treatment crossover study reports on half (n = 27) of the trial population and showed more patient preference for crossover to SCS.
9	**North et al, 2005*** RCT	This study reported benefits of spinal cord stimulation for FBSS compared to reoperation. However, 39% of eligible patients did not participate in the study because they preferred reoperation. This study has a small sample size and high rate of cross-over.
10	**North et al, 2007*** Economic Evaluation	The study had small numbers, small absolute differences, wide confidence intervals, and a high level of crossover.
11	**Turner et al, 2010***** Prospective Cohort Trial	The study found no evidence for greater effectiveness of SCS versus alternative treatments in this patient population (worker's compensation) after 6 months.

* Indicates that study or author(s) received industry funding.
** All logistical aspects of the study were managed and funded by industry.
*** This study was funded by the Department of Labor and Industries of Washington State.

Figure 1: Kemler Study Design

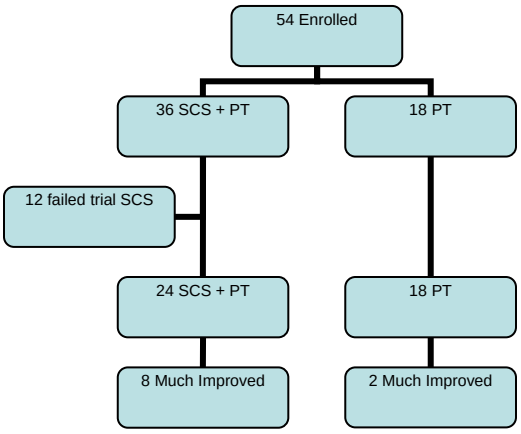

Figure 2: Kumar Study Design

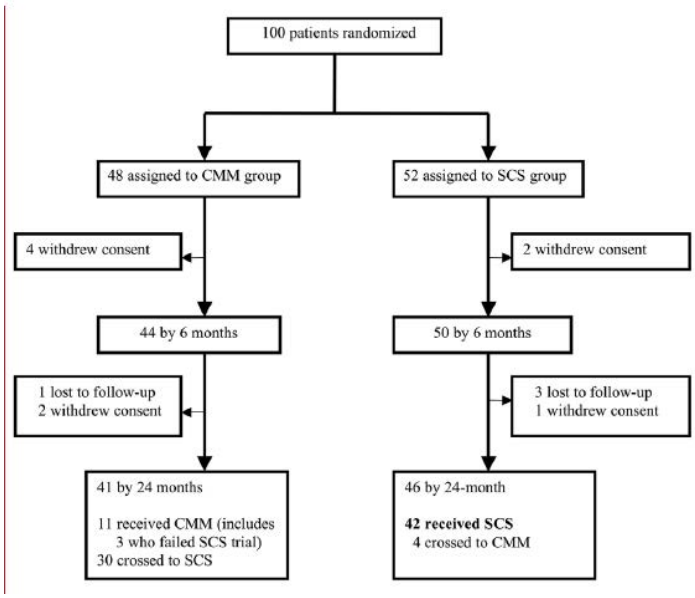

Figure 3: North Study Design

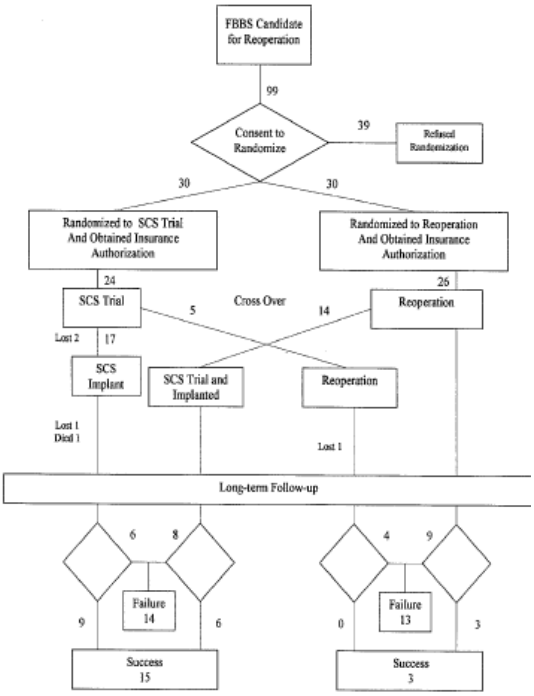

Figure 4: Turner Study Design

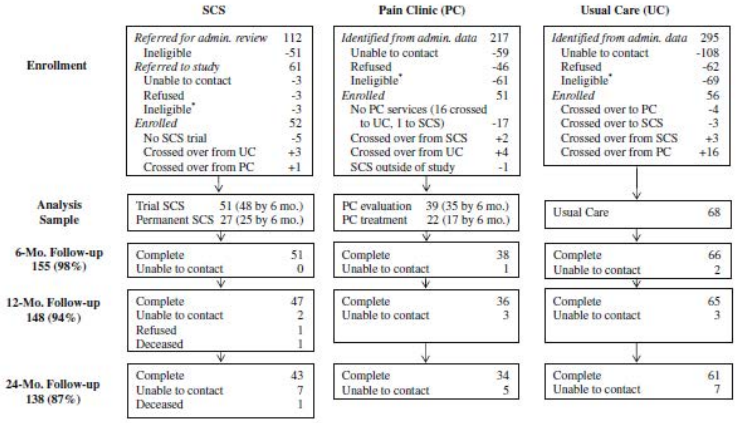

Table 2: Systematic Reviews

Studies	Author and Source	Abstract
5,9, 10	**Bala et al, 2008** *Clinical Journal of Pain*	SCS may be effective in the treatment of FBSS in terms of pain reduction. SCS was found to be more effective and less costly in the long term. Funded by the Dutch Health Care Insurance Board.
1,6,7,8,9,10	**Frey et al, 2009*** *Pain Physician*	The effectiveness of SCS in relieving chronic intractable pain of failed back surgery syndrome is Level II-1 or II-2 for clinical use on a long-term basis.
1,2,3,7,8	**Mailis-Gagnon et al, 2004** Cochrane Collaborative	There is limited evidence in favor of SCS for FBSS and CPRS-1; more trials are needed for confirmation.
1,2,3,7,8	**Mailis-Gagnon et al, 2009** Cochrane Collaborative	No changes were made to the previous analysis.
6,7,8,9	**Simpson et al, 2009** *Health Technology Assessment*	The evidence suggested that SCS was effective in reducing the chronic neuropathic pain of FBSS and CRPS type I. For ischaemic pain, there may need to be selection criteria developed for CLI, and SCS may have clinical benefit for refractory angina short term. Further trials of other types of neuropathic pain or subgroups of ischaemic pain, may be useful.
3	**Taylor et al, 2004*** *Journal of Pain and Symptom Management*	The initial healthcare acquisition costs of SCS implantation are consistently offset by a reduction in post-implant healthcare resource demand.
1	**Taylor et al, 2006*** *European Journal of Pain*	SCS appears to be an effective therapy in the management of patients with CRPS-1 (Level A evidence) and CRPS-2 (Level D evidence). Moreover, there is evidence to demonstrate that SCS is a cost-effective treatment for CRPS-1.
3,9	**Taylor et al (a), 2006*** *Journal of Pain and Symptom Management*	The results support the use of SCS in patients with refractory neuropathic back and leg pain/FBSS (B) and CRPS-1 (A) -2(D).
1,3	**Turner et al, 2004**** *Pain*	Physical therapy plus SCS, compared with PT alone, had a statically significant but clinically modest effect at 6 and 12 months in relieving pain with SCS. Stronger studies are needed to provide more definitive data.

* Indicates that study or author(s) received industry funding.
** The review received no industry funding, but was funded by the Medical Aid Fund of the Washington State Department of Labor and Industries. One of the three authors has received research grant support from, and has served as a lecturer and consultant, for industry.

Table 3: Guidelines

Author/Date Source	Organization	Summary
American Society of Anesthesiologists, 2010 *Anesthesiology*	American Society of Anesthesiologists (ASA)	SCS may be used in the multimodal treatment of persistent radicular pain in patients who have not responded to other therapies (e.g., patients with CRPS). A trial should be performed before considering permanent implantation of the device.
Chou, 2009 *Spine*	American Pain Society	The authors found benefit from SCS for FBSS.
National Institute for Health and Clinical Excellence (NICE), 2009	National Institute for Health and Clinical Excellence (NICE)	Guidance based on TA by Simpson et al (Health Technology Assessment). As no references are included in this document, the recommendations are not admissible in this report.
Crucco et al, 2007* *European Journal of Neurology*	European Federation of Neurological Societies(EFNS)	B level evidence for the effectiveness of SCS in FBSS and CRPS-1. Five of the eight authors had industry funding.
Institute for Clinical Systems Integration (2009)	Institute for Clinical Systems Integration (ICSI)	SCS for chronic low back pain resistant to adequate conservative therapy holds promise but has limited scientific evidence.
Boswell, 2007* *Pain Physician*	American Society of Interventional Pain Physicians	Recommends use of SCS for managing patients with FBSS.
Reflex Sympathetic Dystrophy Syndrome Association (RSDSA), 2006*	Reflex Sympathetic Dystrophy Syndrome Association (RSDSA)	Promotes a stepwise progression of treatment, from less invasive to more invasive (including SCS), for patients with persistent CRPS.

* Indicates that study or author(s) received industry funding.

APPENDIX B:
Principles for Assessing the Quality of Evidence

AMSTAR (Assessment of Multiple Systematic Reviews)[1]

AMSTAR is a measurement tool created to assess the methodological quality of systematic reviews. Each of the questions below is answered with one of the following:
_ Yes
_ No
_ Can't answer
_ Not applicable

1. Was an 'a priori' design provided?
The research question and inclusion criteria should be established before the conduct of the review.

2. Was there duplicate study selection and data extraction?
There should be at least two independent data extractors and a consensus procedure for disagreements should be in place.

3. Was a comprehensive literature search performed?
At least two electronic sources should be searched. The report must include years and databases used (e.g. Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated and where feasible the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found.

4. Was the status of publication (i.e. grey literature) used as an inclusion criterion?
The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc.

5. Was a list of studies (included and excluded) provided?
A list of included and excluded studies should be provided.

6. Were the characteristics of the included studies provided?
In an aggregated form such as a table, data from the original studies should be provided on the participants, interventions and outcomes. The ranges of characteristics in all the studies analyzed e.g. age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported.

7. Was the scientific quality of the included studies assessed and documented?
'A priori' methods of assessment should be provided (e.g., for effectiveness studies if the author(s) chose to include only randomized, double-blind, placebo controlled studies, or allocation concealment as inclusion criteria); for other types of studies alternative items will be relevant.

8. Was the scientific quality of the included studies used appropriately in formulating conclusions?
The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations.

9. Were the methods used to combine the findings of studies appropriate?
For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e. Chi-squared test for homogeneity, I2). If heterogeneity exists a random effects model should be used and/or the clinical appropriateness of combining should be taken into consideration (i.e. is it sensible to combine?).

10. Was the likelihood of publication bias assessed?
An assessment of publication bias should include a combination of graphical aids (e.g., funnel plot, other available tests) and/or statistical tests (e.g., Egger regression test).

11. Was the conflict of interest stated?

[1] Shea, BJ et al. Development of AMSTAR: A Measurement Tool to Assess the Methodological Quality of Systematic Reviews. *BMC Medical Research Methodology* (2007); 7(10).

Cochrane Collaboration: Criteria List for the Methodological Quality Assessment of Individual Studies[2]

The Cochrane criteria assess the quality and internal validity of individual trials. Each of the questions below is answered with one of the following:

_ Yes
_ No
_ Don't Know

1. **Was the method of randomization adequate?**
   A random (unpredictable) assignment sequence. Examples of adequate methods are computer generated random number table and use of sealed opaque envelopes. Methods of allocation using date of birth, date of admission, hospital numbers, or alternation should not be regarded as appropriate.

2. **Was the treatment allocation concealed?**
   Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient.

3. **Were the groups similar at baseline regarding the most important prognostic indicators?**
   In order to receive a "yes", groups have to be similar at baseline regarding demographic factors, duration and severity of complaints, percentage of patients with neurological symptoms, and value of the main outcome measure(s).

4. **Was the patient blinded to the intervention?**
   The reviewer determines if enough information about the blinding is given in order to score a "yes".

5. **Was the care provider blinded to the intervention?**
   The reviewer determines if enough information about the blinding is given in order to score a "yes".

6. **Was the outcome assessor blinded to the intervention?**
   The reviewer determines if enough information about the blinding is given in order to score a "yes".

7. **Were cointerventions avoided or similar?**
   Cointerventions should either be avoided in the trial design or similar between the index and control groups.

8. **Was the compliance acceptable in all groups?**
   The reviewer determines if the if the compliance to the interventions is acceptable, based on the reported intensity, duration, number and frequency of sessions for both the index intervention and control intervention(s).

9. **Was the drop-out rate described and acceptable?**
   The number of participants who were included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and drop-outs does not exceed 20% for short-term follow-up and 30% for long-term follow-up and does not lead to substantial bias a "yes" is scored. (N.B. these percentages are arbitrary, not supported by literature.)

10. **Was the timing of the outcome assessment in all groups similar?**
    Timing of outcome assessment should be identical for all intervention groups and for all important outcome measurements.

11. **Did the analysis include an intention-to-treat analysis?**
    All randomized patients are reported/analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values) irrespective of noncompliance and co-interventions.

[2] van Tulder, M et al. Updated Method Guidelines for Systematic Reviews in the Cochrane Collaboration Back Review Group. *SPINE* (2003); 28(12): 1290-1299.

Spinal Fusion

Health Services Advisory Council

Evidence Summary

April 12, 2007

Minnesota Department of **Human Services**

Background/Context

Low back pain is extremely common in the United States, accounting for the second most visits to primary care physicians overall (after the common cold).[1] It is estimated that 65-80% of Americans experience back pain at some point in their lives, and roughly 5% of this group will have chronic back pain, largely caused by degenerative disc disease (DDD) – the leading cause of pain and disability in the United States.[1,2] Spinal fusion, or spinal arthrodesis, is a surgical treatment used to control back pain by fusing adjacent vertebrae together and immobilizing them in order to decrease painful movement caused by the pinching of nerves or bone on bone contact.[3] Fusion is typically achieved through the growth of transplanted bone (known as "autografting") and additional devices such as cages, plates and screws are sometimes used to increase stability and promote bone growth.[4]

Rates of spinal fusion surgeries have been increasing dramatically nationwide for over a decade, and rates have been shown to vary considerably by geographic region. A recent study from the Dartmouth Atlas Project used Medicare data to show that lumbar fusion rates rose from 0.3 surgeries per 1000 enrollees in 1992 to 1.1 per 1000 in 2003, an increase of 267%, with a corresponding inflation-adjusted spending increase of over 500%.[5] (In the MHCP fee-for-service population, spinal fusion rates held relatively steady from 2001 through 2005, averaging 1.2 per 1000 member years.) The Dartmouth Atlas study also demonstrated that in 2002 and 2003 nationwide geographic rates of spinal fusion procedures varied nearly 20-fold – the largest coefficient of variation of the surgical procedures studied.[6] This sharp variation in practice patterns suggests a lack of professional consensus on the proper indications for spinal fusion surgery, which have widened over time to include pain from degenerative disorders. Although spinal fusions were originally used primarily to treat severe scoliosis, spinal tuberculosis, and fractures, currently roughly 75% of spinal fusions are performed for spondylosis, disc disorders, and spinal stenosis without deformities.[7] Despite the favorable reimbursement for spinal fusion procedures, their defenders cite improved diagnostic tools, better understanding of the structural causes of back pain, and an aging population with higher expectations for physical function later in life as justifiable reasons for the dramatic increase in their use.[8] Additionally, concerns have been raised about the efficacy of spinal fusion procedures for degenerative disc disease (DDD) relative to less invasive courses of treatment.[9] It is important for DHS to ensure that the considerable public expenditures devoted to spinal fusion surgeries result in clinical benefit and positive outcomes.

In response to these issues, the 2005 legislature mandated that the department institute evidence-based criteria to identify when and for whom spinal fusion surgeries will be authorized. These procedures currently require prior authorization, and the criteria in use are attached as *Appendix A*. The review of the evidence that follows places these criteria in the context of the available research, and proposes changes to them based on the current state of the evidence.

Summary of Evidence

The evidence reviewed for this document includes three sets of clinical guidelines and three systematic reviews, as well as a technology assessment of lumbar artificial intervertebral discs which addresses spinal fusion as well. The guidelines come from the American Association of Neurological Surgeons/Congress of Neurological Surgeons (published in the *Journal of Neurosurgery: Spine* in 2005), the Washington State Department of Labor and Industries (2002), and the Work Loss Data Institute (2006). The systematic reviews come from the Cochrane Collaboration (2006), ECRI (2005), and UpToDate (2006), and the technology assessment from ICSI (2005).

The guidelines consistently recommend consideration for spinal fusion in patients with spinal deformity or instability (including stenosis associated with spondylolisthesis), fracture, dislocation, infection, and progressive neurological deficit. In the absence of these indications, all three of the guidelines reviewed recommend a course of conservative therapy prior to consideration for spinal fusion surgery, specified as no shorter than three months. The AANS/CNS and Washington State guidelines further evaluate the relative efficacy of spinal fusion in a number of clinical scenarios.

Beyond the structural indications listed above, there is far less consistency in the guidelines. The AANS/CNS cite high-quality evidence to support their recommendation that spinal fusion be considered for "carefully selected patients with low back pain [without stenosis or spondylolisthesis] intractable to the best medical management", while acknowledging that evidence exists (graded as lower-quality) showing spinal fusion to be equally as effective as cognitive and physical therapy for these patients. The Washington State Department of Labor and Industries guidelines add further indications for spinal fusion when patients have had prior back surgery. For patients with prior laminectomy, discectomy, or other decompressive procedure at the same vertebral level, the Washington State guidelines add signs and symptoms of neurogenic claudication or lumbar radiculopathy and loss of facet surface area to the above indications for spinal fusion. For patients with a prior spinal fusion at the same level, they recommend consideration of surgery for patients with neurogenic claudication, lumbar radiculopathy, and pseudoarthrosis. Patients with prior surgery at a different vertebral level are subject to the same criteria as those with no prior surgery.

The systematic reviews and technology assessment underscore the ambiguity of the evidence surrounding spinal fusion surgery for degenerative disc disease (spondylosis) absent deformity or instability. While some randomized trials have shown spinal fusion to be superior to conservative treatment in patients with chronic back pain, others have shown long term outcomes for spinal fusion patients to be equivalent to those receiving conservative treatments.[10] Many of the studies reviewed have rather short follow-up periods not exceeding two to three years, and are difficult to compare due to non-standardized approaches to conservative treatment. There is conflicting evidence regarding the efficacy and outcomes of spinal fusion for degenerative disc disease.

Existing Prior Authorization Criteria and Potential Changes

The current MHCP prior authorization criteria for spinal fusion are attached as *APPENDIX A* and are generally consistent with the clinical evidence reviewed. The indications of spinal deformity or instability are addressed, as is pseudoarthrosis. "Chronic discogenic back pain without instability" is listed as a condition supporting medical necessity following failed conservative therapy despite the mixed evidence of its efficacy. All of the authorization criteria require radiographic documentation for approval.

The review of the evidence highlights a number of potential changes to the prior authorization criteria:

- The current criteria indicate that the conditions supporting medical necessity listed are not definitive, leaving the door open for other indications to be approved. The criteria could be tightened so that an exhaustive list of indications would constitute the only approved conditions.

- The additional indications for spinal fusion in patients with prior spinal surgery listed in the Washington State Department of Labor and Industries guidelines could be added to the prior authorization criteria:

    - For patients with prior laminectomy, discectomy, or other decompressive procedures at the same vertebral level, spinal fusion will be considered for patients with any of the following:
        - neurogenic claudication
        - lumbar radiculopathy
        - loss of facet surface area
    - For patients with a prior spinal fusion at the same level, spinal fusion will be considered for patients with any of the following:
        - neurogenic claudication
        - lumbar radiculopathy
        - pseudoarthrosis

- The criteria could draw from the guidelines and specify that for patients with "chronic discogenic back pain without instability" the trial of conservative care required before surgery be no shorter than 3 months in duration. The conflicting nature of the evidence surrounding spinal fusion for discogenic pain (low back pain from degenerative discs without sciatica) has led to recent calls for more evidence to be gathered from clinical trials before it is considered an accepted indication for surgery.[11,12] However, in the absence of definitive evidence of its efficacy (or lack of efficacy), the requirement of conservative care and "the absence of other sources of pain and underlying psychosocial issues" prior to surgery may be a reasonable compromise.

References

[1] Institute for Clinical Systems Improvement. *Technology Assessment Report: Lumbar Intervertebral Discs.* Bloomington, MN. (2005).

[2] Lipson SJ. Spinal-Fusion Surgery – Advances and Concerns. *The New England Journal of Medicine.* (2004); 350(7):643-4.

[3] ECRI. Custom Hotline Response: Guidelines for Spinal Fusion. Plymouth Meeting, PA. (2005).

[4] UpToDate, Inc. *Treatment of Chronic Low Back Pain.* Waltham, MA. (2006).

[5] Weinstein JN, et al. United States' Trends and Regional Variations in Lumbar Spine Surgery: 1992-2003. *Spine.* (2006);31(23):2707-14.

[6] ibid.

[7] Deyo RA, et al. Spinal-Fusion Surgery – The Case for Restraint. *The New England Journal of Medicine.* (2004); 350(7):722-6.

[8] Errico TJ, et al. A Fair and Balanced View of Spine Fusion Surgery. *The Spine Journal.* (2004);4:129S-142S.

[9] Institute for Clinical Systems Improvement.

[10] Gibson JA and Waddell G. Surgery for Degenerative Lumbar Spondylosis. *Cochrane Database of Systematic Reviews.* (2005);2:CD001352.

[11] Deyo RA, et al.

[12] Gibson JA and Waddell G.

Guidelines and Reviews Consulted

Gibson JA and Waddell G. Surgery for Degenerative Lumbar Spondylosis. *Cochrane Database of Systematic Reviews*. (2005);4:CD001352. (abstract only)

ECRI. *Custom Hotline Response: Guidelines for Spinal Fusion*. Plymouth Meeting, PA. (2005).

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UpToDate, Inc. *Treatment of Chronic Low Back Pain*. Waltham, MA. (2006).

Washington State Department of Labor and Industries. *Guidelines for Lumbar Fusion (Arthrodesis)*. Olympia, WA. (2002).

Work Loss Data Institute. *Low Back – Lumbar & Thoracic (Acute & Chronic)*. Corpus Christi, TX. (2006).

Existing Clinical Guidelines and Meta-Analyses Reviewed

Organization/Title/Year **Method to Analyze Evidence**	**Scope**	**Objectives**	**Methods to Make Recommendations/ Conclusions**
Cochrane Collaboration: *Surgery for Degenerative Lumbar Spondylosis* 2005 (International Non-Profit Organization) **Systematic Review**	Treatment	To assess current scientific evidence on the effectiveness of surgical interventions for degenerative lumbar spondylosis.	Expert Opinion
ECRI: *Custom Hotline Response: Guidelines for Spinal Fusion* 2005 (Non-profit Research Agency) **Systematic Review**	Treatment	To provide an overview of the available guidelines for spinal fusion.	Expert Opinion
Institute for Clinical Systems Improvement: *Technology Assessment Report: Lumbar Intervertebral Discs* 2005 (Private Non-Profit Organization) **Systematic Review**	Treatment	To assess the safety and efficacy of lumbar artificial intervertebral discs, as well as alternative treatments including spinal fusion.	Expert Opinion
Journal of Neurosurgery: Spine/ American Assoc. of Neurological Surgeons and Congress of Neurological Surgeons: *Guidelines for the Performance of Fusion Procedures for Degenerative Disease of the Lumbar Spine* 2005 (Journal Article/Medical Specialty Society) **Systematic Review**	Diagnosis Evaluation Treatment	To perform an evidence-based review of the literature on lumbar fusion procedures for degenerative disease of the lumbar spine and to formulate treatment recommendations based on this review.	Expert Consensus
UpToDate, Inc.: *Treatment of Chronic Low Back Pain* 2006 (Private Independent Organization in Cooperation with Medical Specialty Societies) **Systematic Review**	Evaluation Treatment	To assess the most current information on the treatment of chronic low back pain.	Expert Opinion

Organization/Title/Year **Method to Analyze Evidence**	**Scope**	**Objectives**	**Methods to Make Recommendations/ Conclusions**
Washington State Dept. of Labor and Industries: *Guidelines for Lumbar Fusion* 2002 (State Government Agency) **Literature Review**	Evaluation Treatment	To serve as an instructional aid for physicians when treating injured workers who present with low back pain and associated symptoms…and who have no evidence of spinal fracture. To provide…the information necessary to make recommendations about the medical necessity and clinical appropriateness of spinal fusions.	Expert Opinion
Work Loss Data Institute: *Low Back – Lumbar & Thoracic (Acute & Chronic)* 2006 (Public For-Profit Organization) **Systematic Review**	Diagnosis Evaluation Management Treatment	To offer evidence-based step-by-step decision protocols for the assessment and treatment of workers' compensation conditions.	Expert Opinion

APPENDIX A:
Current MHCP Prior Authorization Criteria for Spinal Fusion

Procedure Codes: 22532, 22533, 22534, 22548, 22554, 22556, 22558, 22585, 22590, 22595, 22600, 22610, 22612, 22614, 22630, 22632, 22800, 22802, 22804, 22808, 22810, 22812
****

Cervical, thoracic, and lumbar fusions WILL BE approved as medically necessary.

Lumbar fusions WILL NOT be approved as medically necessary for the management of the following conditions:

1. With initial primary laminectomy/discectomy for nerve root decompression without documented instability.
2. Multiple-level degenerative disc disease (more than 2 levels).
3. Lapraroscopic anterior interbody fusion will not be approved as it is considered investigative.

A. Lumbar fusions WILL BE approved as medically necessary for **ANY** of the following conditions when confirmed by radiographic studies:

1. Neural compression after spinal fracture (involving 2 or 3 spinal levels).
2. Pseudarthrosis.
3. Epidural compression or vertebral destruction from tumor.
4. Spinal tuberculosis.
5. Instability after debridement for infection.
6. Idiopathic scoliosis over 40 degrees or progressive degenerative scoliosis.
7. Other causes of symptomatic instability with compression of either the nerve root or the cauda equina.

B. Lumbar fusions WILL BE approved as medically necessary for the treatment of degenerative conditions with spinal instability when all of the following criteria are met:

1. Documented unremitting pain and disability that is refractory to conservative therapy for at least 12 months.

-AND-

2. Radiographic documentation (plain radiographs, MRI, and/or CT scans) of spinal instability (> 3 mm of translation and 10 degrees or more of angulation of one vertebra compared to the adjacent vertebra in a spinal motion segment).

-AND-

3. Either a) or b) below:
    a. Spinal stenosis decompression for ANY ONE OF THE FOLLOWING:
        - Spondylolisthesis.
        - Flexible or progressive degenerative scoliosis or kyphosis.
        - Intraoperative excessive facet removal.
        - Associated radical discectomy.
        - Removal of par interaticularis or pars fracture.
        - Recurrent spinal stenosis at the same segment.

    -OR-

    b. Post-laminectomy instability.

C. Lumbar fusions WILL BE approved as medically necessary for chronic discogenic back pain alone (without instability) when all of the following conditions have been met:

1. Documented unremitting pain and disability that is refractory to conservative therapy for at least 12 months.

-AND-

2. Radiographically documented degenerative disc disease limited to 1 or 2 lumbar levels.

-AND-

3. Concordant pain reproduced on provocative discography testing at 1 or 2 levels that correlates with MRI findings and post-discography CT scan disc morphology imaging.

-AND-

4. Elimination of all other sources of pain.

-AND-

5. Absence of underlying psychosocial issues (e.g., depression, drug or alcohol abuse).

APPENDIX B:
HSAC Process for Summarizing Evidence

Background: HSAC, in conjunction with the DHS Medical Director, is charged with advising the Department on clinical issues to inform decision-making on coverage and benefit policy. Where applicable, DHS produces summaries of existing clinical evidence to ensure that these decisions are based on the most up-to-date and reliable clinical evidence as well as the expertise of the Council's members.

Sources: The key sources used to gather evidence is gathered are summarized below:

- **Medicaid-Specific Collaborations:** Two key organizational collaborations provide a starting point for the evaluation of topics, helping to frame clinical questions and serving as channels for consultation with other states' programs in making evidence-based coverage decisions.
    - Medicaid Evidence-Based Decisions (MED) Project – A collaboration of state Medicaid programs housed at the Center for Evidence-Based Policy at Oregon Health & Science University. MED Project creates reports and recommendations based upon clinical evidence, provides staff support and facilitates knowledge sharing between states.
    - AHRQ/AcademyHealth Medicaid Medical Directors' Learning Network – A forum for the sharing of research and experience among medical directors in state Medicaid programs across the country.
- **Keyword Searches:** Topical keyword searches are then performed, searching for clinical guidelines and relevant peer-reviewed articles using the following sources:
    - AHRQ National Guidelines Clearinghouse – A clearinghouse of recommended guidelines from medical specialty societies, private non-profit organizations, and evidence-based practice centers.
    - The Cochrane Library – An international database of clinical practice guidelines. (Access to full-text resources is somewhat limited currently.)
    - Medline (Full-Text Only) – The National Library of Medicine's bibliographic database and search engine.
- **Resources Accessed Directly:** Other sources are routinely accessed directly in search of clinical guidelines and peer-reviewed articles:
    - AHRQ Evidence-Based Program – A repository of rigorous clinical reports from grant-funded evidence-based practice centers across the U.S. and Canada.
    - Institute for Clinical Systems Improvement (ICSI) – A locally-based, nationally recognized collaboration of health care organizations that identifies best clinical practices and facilitates their implementation.
    - Journal Subscriptions:
        - New England Journal of Medicine
        - Health Affairs
    - Technology Assessments:
        - Blue Cross and Blue Shield Association Technology Evaluation Center
        - ECRI (Access provided through the MED Project)
        - ICSI

Process: After information is gathered and reviewed, sources are chosen with a preference for clinical practice guidelines (from professional organizations or independent non-profits), meta-analyses and systematic reviews, supplemented by quality peer-reviewed primary articles. Preference is also given to the most up-to-date evidence available. Summary documents are then created, providing brief background and context for the clinical issue, the amount, quality, and reliability of the evidence, and proposed action to be taken based upon that evidence. These documents are reviewed internally among DHS staff (including physicians) before coming before HSAC. HSAC uses these summary documents as a starting point for discussion around the issue in question, drawing upon their assessment of the evidence and their clinical expertise to advise DHS.

Spinal Fusion vs. Conservative Therapy

Health Services Advisory Council

Evidence Summary

September 10, 2007

Minnesota Department of **Human Services**

Background/Context

During a series of meetings in 2007, the DHS Health Services Advisory Council (HSAC) examined the evidence for spinal fusion surgeries in order to make recommendations on the existing prior authorization (PA) criteria for these procedures. There is agreement in the evidence that spinal fusion is warranted in cases of spinal deformity or instability, dislocation, infection, and progressive neurological deficit. The bulk of the Council's discussion centered on surgery for patients with chronic discogenic back pain due to degenerative discs: the population for which much of the controversy exists surrounding indications for surgery. The current criteria require that patients with these conditions undergo a trial of conservative therapy for at least 12 months before consideration for surgery. However, the criteria do not specify the exact components of this therapy.

HSAC expressed a desire to add specificity to the required course of conservative therapy, including listing the precise requirements and quantities of therapy. DHS and HSAC will solicit feedback from spine experts and draw from the clinical evidence base to determine the characteristics of efficacious non-surgical therapies. The evidence summary that follows is intended to guide the discussion and drafting of the coverage policy. It is arranged in two subsections: elements of conservative therapy drawn from randomized trials, and elements drawn from systematic reviews.

Summary of Evidence

Randomized Trials

A handful of well-known randomized clinical trials have compared spinal fusion with conservative (non-surgical) therapy for patients with chronic low back pain. As discussed in the HSAC Evidence Review for Spinal Fusion, the results of these trials are conflicting. However, the courses of conservative therapy leading to equivalent or superior outcomes in these studies can inform the requirements for the DHS PA criteria.

1) A 2005 randomized controlled trial (RCT) published in the British Medical Journal (BMJ)[i] compared spinal fusion with a rehabilitation program in patients with chronic low back pain. Two years later, both groups demonstrated reductions in disability, with the surgery group experiencing slightly better outcomes. The difference between the groups narrowly met the predefined criterion for minimal clinical difference. Given the additional risk and cost of surgery, the authors concluded that no clear evidence emerged showing that surgery led to better outcomes than rehabilitation. The intensive rehabilitation program consisted of education and exercise, with patients participating five days a week for three weeks. Most outpatient centers offered 75 hours of intervention (ranging from 60 to 110 hours), and one day follow-up sessions occurred following treatment at one, three, six, or 12 months. Sessions were led by physiotherapists, and included clinical psychologists and medical support. Exercises were tailored to each patient's baseline ability, and were intended to increase daily repetitions and duration. Hydrotherapy was also administered daily, and principles of cognitive behavioral therapy were used to identify and overcome pain-related fears and unhelpful beliefs.

2) A Norwegian randomized trial,[ii] published in 2003, compared instrumented spinal fusion surgery with cognitive and exercise therapy in patients with chronic low back pain and disc degeneration. After one year, both groups showed equal improvement in disability and a number of other measures. The exercise and cognitive interventions consisted of lectures by physical medicine and rehabilitation experts focusing on the anatomic sources of pain, the interplay between structures, and education regarding the importance of engaging in activity and using the back. Additionally, individually-tailored exercises were developed based on goals created through patient questionnaires and physical test results. Supervised treatment lasted one week initially, followed by two weeks at home and an additional treatment period of two weeks during which the intensity of physical activity was increased. On average, the duration of the rehabilitation program was 25 hours per week.

   An additional RCT by the same lead author[iii] was composed of patients with chronic low back pain following previous surgery for disc herniation, and utilized the same conservative therapy approach described above. This study demonstrated no benefit (measured by functional disability and pain) of spinal fusion surgeries over this course of cognitive intervention and exercises.

3) Another RCT, conducted by the Swedish Lumbar Spine Study Group[iv] and published in 2001, compared lumbar spinal fusion with non-surgical therapy in patients with chronic low back pain. After two years, the spinal fusion group saw greater reductions in back pain and disability than the conservative therapy group. Non-surgical therapy in this study was not standardized, meaning that patients received a number of different kinds of physical therapy. All patients in this arm of the study received some manner of physical therapy, while some additionally received some combination of cognitive training, acupuncture, education, pharmaceuticals, etc. Additionally, the patient inclusion criteria for both groups mandated that all patients had undergone unsuccessful non-surgical treatment efforts leading up to the study. This raises the possibility that patients randomized to the non-surgical group merely continued unsuccessful efforts rather than patients and providers committing to an intensive rehabilitation program.

4) A 2000 Swedish prospective study[v] randomized patients with isthmic spondylolisthesis to receive either spinal fusion or conservative management. At two-year follow-up, the surgical group showed greater improvement

in disability and pain than the conservative therapy group. Patients in the conservative management arm participated in an exercise therapy program with a physiotherapist, performing 12 exercises focused on strength and posture with an emphasis on back and abdominal muscles. Exercise therapy was supervised by the physiotherapist for a year, with 45-minute therapy sessions three times a week for the first six months and two times a week for the next six months. After one year, patients were instructed to continue with the exercises at home. Two thirds of patients completed the year of supervised therapy, and it is unknown how compliant patients were with continuing therapy at home in the second year.

Systematic Literature Reviews

In addition to trials that directly compare spinal fusion with non-surgical therapies, a number of systematic reviews have evaluated the effectiveness of conservative therapies for chronic low back pain. The results of these reviews provide further information on the characteristics of the rehabilitation programs that work best.

1) A systematic review of multidisciplinary rehabilitation for low back pain[vi] provided evidence that patients receiving "intensive multidisciplinary biopsychosocial rehabilitation with functional restoration"[vii] had greater pain reduction and improved function than those receiving non-multidisciplinary rehab or usual care. Less intensive multidisciplinary interventions were also shown to be no more effective than usual care.

2) Another systematic review looked at RCTs to evaluate the effectiveness of exercise therapy for chronic low back pain.[viii] This 2000 review concluded that the evidence comparing exercise and inactive treatments was conflicting, but that exercise therapy was more effective than usual care by general practitioners and equally as effective as conventional physiotherapy.

3) A third review evaluated RCTs comparing behavioral therapies to reference treatments for chronic, non-specific low back pain.[ix] Results at the time of publication showed strong evidence that behavioral therapy had a moderate to small positive impact on pain, functional status, and behavioral outcomes compared with wait-list controls, as well as conflicting evidence comparing behavioral therapy with other conservative treatments. There was no strong evidence that a particular type of behavioral therapy (such as cognitive, operant, or respondent) was stronger than another.

Conclusions

The randomized trials comparing spinal fusion with non-surgical therapy for chronic degenerative low back pain provide detail regarding the components of effective conservative care. In the trials resulting in outcomes equivalent to spinal fusion, conservative therapy included the following:

- A combination of exercise therapy and cognitive/behavioral components.
- Exercise therapy that increased in repetition and duration.
- The duration of the intensive therapy ranged from three to five weeks, averaging roughly 75 to 100 total hours of intervention. Most therapy sessions occurred daily on consecutive days, with follow-up sessions at an average of six months to evaluate pain and function.

The systematic reviews identify some of the broad characteristics of effective conservative therapy:

- Multidisciplinary rehabilitation is more effective than single-modality approaches.
- Higher-intensity conservative therapy programs are more effective than lower-intensity therapy.
- Both exercise therapies and behavioral therapies have been shown to have modest beneficial effects (when administered separately) compared with usual care.

Recommendations

The PA criteria in place for spinal fusion surgeries require a 12-month trial of conservative therapy prior to surgery for patients with chronic discogenic back pain without instability and patients with degenerative conditions and instability. The available literature suggests requiring that the conservative therapy:

- Have both exercise therapy and cognitive/behavioral components.

- Involve a total of at least 50 hours of therapy, including at least three consecutive weeks of intensive therapy.

- Include at least one follow-up visits, no less than three months following therapy, to assess disability and pain. If the clinician deems that the patient has shown significant improvement, the 12-month requirement begins anew.

References

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[ii] Brox JI, et al. Randomized Clinical Trial of Lumbar Instrumented Fusion and Cognitive Intervention and Exercises in Patients with Chronic Low Back Pain and Disc Degeneration. *Spine* (2003);28(17):1913-21.

[iii] Brox JI, et al. Lumbar Instrumented Fusion Compared with Cognitive Intervention and Exercises in Patients with Chronic Back Pain After Previous Surgery for Disc Herniation: A Prospective Randomized Controlled Study. *Pain* (2006);122:145-55.

[iv] Fritzell P, et al. 2001 Volvo Award Winner in Clinical Studies: Lumbar Fusion Versus Nonsurgical Treatment for Chronic Low Back Pain. *Spine* (2001);26(23):2521-34.

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Surgical Treatment of Gastroesophageal Reflux Disease (GERD) in Adults

Health Services Advisory Council

Evidence Summary

October 16, 2008

Minnesota Department of **Human Services**

Background/Context

Gastroesophageal reflux disease (GERD) is defined as symptoms or mucosal damage caused by abnormal acid exposure of the esophagus. The estimated prevalence of weekly heartburn and/or acid regurgitation in developed countries is 10-20%, and the direct treatment costs of GERD in the United States topped $10 billion in 2000.[1] Diagnosis of GERD is often challenging because the principal symptoms of GERD (heartburn, regurgitation, and dysphagia) are commonly seen in patients who do not have abnormal acid exposure, and symptoms correlate poorly with objective findings such as the degree of mucosal injury on endoscopy and esophageal pH levels.[2] For patients with chronic GERD, the goals of treatment are improvement of symptoms, healing and maintenance of erosive esophagitis, and the prevention of complications (such as Barrett's esophagus, esophageal stricture formation, or esophageal adenocarcinoma).[3] The long-term treatment of GERD usually involves the use of over-the-counter or prescription medications such as histamine type 2 receptor antagonists (H2RAs) and proton pump inhibitors (PPIs), and management strategies can also include endoscopic or surgical approaches.

The surgical treatment of GERD, known as fundoplication, involves the creation of a "wrap" or collar around the esophagus to serve as a barrier to the reflux of all gastric contents. Fundoplication has become increasingly popular with the advent of less-invasive laparoscopic techniques.[4] While surgery can be an alternative to a lifetime of medication therapy, there is uncertainty among clinicians about the comparative effectiveness and safety of medical vs. surgical therapy – especially considering the high degree of patients who still require antireflux medications after surgery.

In the Minnesota Health Care Programs (MHCP) fee-for-service population, reimbursement for GERD surgeries (excluding pharmacy costs) totaled $1.1 million in 2007 – down from a 5-year high of $3.3 million in 2005. The majority of fundoplication procedures in this population are performed on adults and billed under esophageal reflux diagnoses. The high unit cost of these procedures and the lack of consensus regarding the optimal management of chronic GERD make it worthwhile to examine the evidence of their effectiveness to ensure that MHCP coverage policy reflects it.

Summary of Evidence

The evidence reviewed for this document includes a high-quality systematic review, three randomized controlled trials published after the systematic review, and three sets of clinical practice guidelines.

The federal Agency for Healthcare Research and Quality (AHRQ) published a systematic review in 2005 comparing the effectiveness of management strategies for GERD. The first review prepared under AHRQ's Effective Health Care Program, the paper compares patient outcomes between medical, surgical, and endoscopic therapies.

- The AHRQ review concluded that medical therapy (with a PPI regimen) and fundoplication were similarly effective for improving symptoms and decreasing acid exposure. Additionally, it concluded that the available evidence did not support a benefit of fundoplication over medical therapy for preventing Barrett's esophagus or esophageal adenocarcinoma, and noted that studies reported that 10 to 65% of surgical patients continued to require medications. While acknowledging that the body of evidence meeting the selection criteria for this comparison was limited to three head-to-head trials,[5] the authors stated that their methodological quality made them susceptible to some bias but not sufficiently so to invalidate the results.

Three additional randomized controlled trials (RCTs) comparing medical management of GERD with surgery were identified; all were published after the 2005 AHRQ review. Two of the three are longer-term follow-ups of studies included in the AHRQ paper.

- A study by Lundell et al. was published in 2007 in the *British Journal of Surgery* – a seven-year follow-up of the 2001 Lundell et al. 5-year follow-up. In the earlier study, rates of treatment failure between omeprazole and anti-reflux therapy were not statistically significantly different when dose escalation was accounted for. In the seven-year follow-up, the difference in efficacy between the two groups (omeprazole: n=119, surgery: n=99) reached statistical significance in favor of surgery (p=.045) with the proportion of patients in whom treatment did not fail differing by roughly 10%. However, throughout the study interval surgical patients more frequently reported obstructive symptoms such as dysphagia (p=.006), flatulence (p=.001) and inability to belch (p=.001).

- A 2006 study by Mehta et al. in the *Journal of Gastrointestinal Surgery* is a longer (seven-year) follow-up to the 2005 Mahon et al. trial cited in the AHRQ review. The more recent study conducted a symptom questionnaire to evaluate 183 of the 217 patients randomized in the shorter-term study after a median of 6.9 years. Patients were split into three arms: those randomized to PPIs, those randomized to surgery, and those who elected to have surgery from the original PPI group after 12-month follow-up. The authors concluded that all three groups experienced significant improvement in symptom scores after the initial 12-month follow-up, and that both optimal PPI therapy and Nissen fundoplication were effective and durable therapies for GERD. Those who had incomplete symptom relief with PPIs and went on to surgery experienced further symptom relief (p<.01).

- The results of a non-blinded RCT with one-year follow-up by Anvari et al. were published in 2006 in the journal *Surgical Innovation*. Randomizing 52 patients each to medical and surgical arms (n=104), the study showed symptom improvement in the surgical group but not in the medical group (all of whom were already on long-term PPIs). The severity of symptoms was

statistically significantly better in the surgical group compared with the medical group at 12 months ($p<.0001$), but quality of life scores were equivalent.

Three sets of clinical practice guidelines on the management of adults with GERD lend additional context to the evidence review.

- The University of Michigan Health System (2007) published a set of guidelines on the diagnosis and treatment of GERD. The guidelines state that antireflux surgery is an alternative modality in the treatment of GERD for patients with refractory symptoms, noting the high rate of surgical complication (10-20%) and the high rate (>50%) of patients who must return to pre-operative medication regimens.

- The Institute for Clinical Systems Improvement (ICSI) guidelines on the initial management of dyspepsia and GERD, updated in 2006, state that patients with GERD should undergo at least 8 weeks of PPI/antacids and behavioral modification, as well as endoscopy for patients 50 or older or with symptoms of 10 years or greater duration. For patients with positive endoscopy (showing erosions, ulcerations, strictures, or Barret's esophagus) and refractory reflux, the guidelines state that "patients requiring long-term maintenance therapy, or those who are incompletely controlled on maintenance therapy with a single trial of step-down, may wish a surgical opinion regarding fundoplication".

- The Veterans Health Administration and the Department of Defense (VHA/DoD) published a set of primary care guidelines for the management of GERD in 2003. The guidelines state that medical therapy is the first-line management of GERD, but surgery may be an alternative to ongoing medical management in a minority of patients based on individual considerations and preferences. The guidelines also state that surgery "should not be advised with the expectation that antisecretory therapy will no longer be needed or that it is a cancer-preventing procedure."

Summary and Proposed Authorization Criteria

The evidence shows that surgery and medical therapy are similarly effective for the long-term management of chronic GERD. The slight statistical advantage of fundoplication over treatment with medications for symptom management in more recently-published seven-year follow-ups must be balanced against the increased prevalence of long-term side effects associated with surgery and the high proportion of patients who still take PPIs following surgery. GERD surgery has not been shown to reduce the incidence of Barrett's esophagus or cancer compared with medical management. Guidelines suggest that surgery be reserved for patients with refractory GERD when optimal medical management does not provide satisfactory symptom control. An evidence-based coverage policy would limit coverage for GERD surgeries to these patients as well as those with complications putting them at additional risk. A proposed set of authorization criteria follows:

MHCP will cover fundoplication surgeries for the long-term management of adults with chronic GERD as medically necessary. In order for the authorization request to be approved, patients must meet all of the following authorization criteria:

- GERD symptoms are refractory to ongoing medical management for a period of at least six months, which must include:

    - Treatment with proton pump inhibitors (PPIs) and/or histamine type 2 receptor antagonists (H2RAs) with appropriate titration of dosing.
      -AND-
    - Non-pharmacologic management, including lifestyle and behavioral modifications, including dietary changes, body positioning, antacid use, and tobacco cessation if applicable.

  DOCUMENTATION REQUIRED: Written description of medical management and patient's response.

- Patient has undergone a positive endoscopic evalution (showing moderate or severe erosion, ulcerations, strictures, or Barrett's esophagus) after a minimum of 8 weeks of medical management without sufficient symptom relief.

  DOCUMENTATION REQUIRED: Date of endoscopy and written description of findings.

Proposed Codes

CPT

43280 - Laparoscopy, surgical, esophagogastric fundoplasty (eg, Nissen, Toupet procedures)
43324 - Esophagogastric fundoplasty (eg, Nissen, Belsey IV, Hill procedures)
43325 - Esophagogastric fundoplasty; with fundic patch (Thal-Nissen procedure)

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University of Michigan Health System. *Guideline: Gastroesophageal Reflux Disease (GERD)*. Ann Arbor, MI. (2007). WEB LINK TO FULL TEXT

Veterans Health Administration/Department of Defense (VHA/DoD). *VHA/DoD Clinical Practice Guideline for the Management of Adults with Gastroesophageal Reflux Disease in Primary Care Practice*. Washington, DC. (2003). WEB LINK TO FULL TEXT

Table 1: Evidence Consulted

Organization/Title/Year **Method to Analyze Evidence**	**Scope**	**Objectives**	**Methods to Make Recommendations / Conclusions**
Anvari M, et al. 2006 (Journal Article) **Randomized Controlled Trial**	Management Treatment	To compare optimized medical therapy using proton pump inhibitors with laparoscopic Nissen fundoplication in patients with gastroesophageal reflux disease.	Study Results
Institute for Clinical Systems Improvement (ICSI) 2006 (Private Non-Profit Organization) **Systematic Review**	Diagnosis Evaluation Management Treatment	To increase the use of initial treatment recommendations for evaluating gastroesophageal reflux disease (GERD), and to increase appropriate treatment for patients who have ongoing symptoms after initial treatment recommendations.	Expert Consensus
Tufts-New England Medical Center for the Agency for Healthcare Research and Quality (AHRQ) 2005 (U.S. Federal Government Agency) **Systematic Review**	Management Treatment	To examine alternatives for managing the chronic symptoms of uncomplicated GERD in patients who may require long-term treatment.	Expert Consensus
Lundell L, et al. 2007 (Journal Article) **Randomized Controlled Trial**	Management Treatment	To compare long-term outcome after antireflux surgery with acid inhibition therapy in the treatment of chronic gastro-oesophageal reflux disease (GORD).	Study Results
Mehta S, et al. 2006 (Journal Article) **Randomized Controlled Trial**	Management Treatment	To report long –term follow-up data comparing laparoscopic Nissen fundoplication and proton pump inhibitor therapy to treat gastroesophageal reflux disease (GERD).	Study Results
University of Michigan Health System 2007 (Public Academic Institution) **Systematic Review**	Diagnosis Management Treatment	To implement a cost-effective and evidence-based strategy for the diagnosis and treatment of gastroesophageal reflux disease (GERD).	Expert Consensus
Veterans Health Administration, Department of Defense (VHA/DoD) 2003 (U.S. Federal Government Agency) **Systematic Review**	Diagnosis Evaluation Management Treatment	To present options for the initial and long-term management of gastroesophageal reflux disease (GERD) from a primary care perspective. To serve as a tool to aid primary care practitioners in making informed decisions about the diagnosis and pharmacologic treatment of GERD.	Expert Consensus

APPENDIX A:
HSAC Process for Summarizing Evidence

Background: HSAC, in conjunction with the DHS Medical Director, is charged with advising the Department on clinical issues to inform decision-making on coverage and benefit policy. Where applicable, DHS produces summaries of existing clinical evidence to ensure that these decisions are based on the most up-to-date and reliable clinical evidence as well as the expertise of the Council's members.

Sources: The key sources used to gather evidence is gathered are summarized below:

- **Medicaid-Specific Collaborations:** Two key organizational collaborations provide a starting point for the evaluation of topics, helping to frame clinical questions and serving as channels for consultation with other states' programs in making evidence-based coverage decisions.
    - Medicaid Evidence-Based Decisions (MED) Project – A collaboration of state Medicaid programs housed at the Center for Evidence-Based Policy at Oregon Health & Science University. MED Project creates reports and recommendations based upon clinical evidence, provides staff support and facilitates knowledge sharing between states.
    - AHRQ/AcademyHealth Medicaid Medical Directors' Learning Network – A forum for the sharing of research and experience among medical directors in state Medicaid programs across the country.
- **Keyword Searches:** Topical keyword searches are then performed, searching for clinical guidelines and relevant peer-reviewed articles using the following sources:
    - AHRQ National Guidelines Clearinghouse – A clearinghouse of recommended guidelines from medical specialty societies, private non-profit organizations, and evidence-based practice centers.
    - The Cochrane Library – An international database of clinical practice guidelines. (Access to full-text resources is somewhat limited currently.)
    - PubMed and Medline – Medical/health sciences bibliographic databases.
- **Resources Accessed Directly:** Other sources are routinely accessed directly in search of clinical guidelines and peer-reviewed articles:
    - AHRQ Evidence-Based Program – A repository of rigorous clinical reports from grant-funded evidence-based practice centers across the U.S. and Canada.
    - Institute for Clinical Systems Improvement (ICSI) – A locally-based, nationally recognized collaboration of health care organizations that identifies best clinical practices and facilitates their implementation.
    - Technology Assessments:
        - Blue Cross and Blue Shield Association Technology Evaluation Center
        - ECRI Institute (Access provided through the MED Project)
        - ICSI

Process: After information is gathered and reviewed, sources are chosen with a preference for clinical practice guidelines (from professional organizations or independent non-profits), meta-analyses and systematic reviews, supplemented by quality peer-reviewed primary articles. Preference is also given to the most up-to-date evidence available. Summary documents are then created, providing brief background and context for the clinical issue, the amount, quality, and reliability of the evidence, and proposed action to be taken based upon that evidence. These documents are reviewed internally among DHS staff (including physicians) before coming before HSAC. HSAC uses these summary documents as a starting point for discussion around the issue in question, drawing upon their assessment of the evidence and their clinical expertise to advise DHS.

APPENDIX B:
Principles for Assessing the Quality of Evidence

AMSTAR (Assessment of Multiple Systematic Reviews)[i]

AMSTAR is a measurement tool created to assess the methodological quality of systematic reviews. Each of the questions below is answered with one of the following:

_ Yes
_ No
_ Can't answer
_ Not applicable

1. Was an 'a priori' design provided?
The research question and inclusion criteria should be established before the conduct of the review.

2. Was there duplicate study selection and data extraction?
There should be at least two independent data extractors and a consensus procedure for disagreements should be in place.

3. Was a comprehensive literature search performed?
At least two electronic sources should be searched. The report must include years and databases used (e.g. Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated and where feasible the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found.

4. Was the status of publication (i.e. grey literature) used as an inclusion criterion?
The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc.

5. Was a list of studies (included and excluded) provided?
A list of included and excluded studies should be provided.

6. Were the characteristics of the included studies provided?
In an aggregated form such as a table, data from the original studies should be provided on the participants, interventions and outcomes. The ranges of characteristics in all the studies analyzed e.g. age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported.

7. Was the scientific quality of the included studies assessed and documented?
'A priori' methods of assessment should be provided (e.g., for effectiveness studies if the author(s) chose to include only randomized, double-blind, placebo controlled studies, or allocation concealment as inclusion criteria); for other types of studies alternative items will be relevant.

8. Was the scientific quality of the included studies used appropriately in formulating conclusions?
The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations.

9. Were the methods used to combine the findings of studies appropriate?
For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e. Chisquared test for homogeneity, I2). If heterogeneity exists a random effects model should be used and/or the clinical appropriateness of combining should be taken into consideration (i.e. is it sensible to combine?).

10. Was the likelihood of publication bias assessed?
An assessment of publication bias should include a combination of graphical aids (e.g., funnel plot, other available tests) and/or statistical tests (e.g., Egger regression test).

11. Was the conflict of interest stated?
Potential sources of support should be clearly acknowledged in both the systematic review and the included studies.

Cochrane Collaboration: Criteria List for the Methodological Quality Assessment of Individual Studies[ii]

The Cochrane criteria assess the quality and internal validity of individual trials. Each of the questions below is answered with one of the following:

_ Yes
_ No
_ Don't Know

1. **Was the method of randomization adequate?**
   A random (unpredictable) assignment sequence. Examples of adequate methods are computer generated random number table and use of sealed opaque envelopes. Methods of allocation using date of birth, date of admission, hospital numbers, or alternation should not be regarded as appropriate.

2. **Was the treatment allocation concealed?**
   Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient.

3. **Were the groups similar at baseline regarding the most important prognostic indicators?**
   In order to receive a "yes", groups have to be similar at baseline regarding demographic factors, duration and severity of complaints, percentage of patients with neurological symptoms, and value of the main outcome measure(s).

4. **Was the patient blinded to the intervention?**
   The reviewer determines if enough information about the blinding is given in order to score a "yes".

5. **Was the care provider blinded to the intervention?**
   The reviewer determines if enough information about the blinding is given in order to score a "yes".

6. **Was the outcome assessor blinded to the intervention?**
   The reviewer determines if enough information about the blinding is given in order to score a "yes".

7. **Were cointerventions avoided or similar?**
   Cointerventions should either be avoided in the trial design or similar between the index and control groups.

8. **Was the compliance acceptable in all groups?**
   The reviewer determines if the if the compliance to the interventions is acceptable, based on the reported intensity, duration, number and frequency of sessions for both the index intervention and control intervention(s).

9. **Was the drop-out rate described and acceptable?**
   The number of participants who were included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and drop-outs does not exceed 20% for short-term follow-up and 30% for long-term follow-up and does not lead to substantial bias a "yes" is scored. (N.B. these percentages are arbitrary, not supported by literature.)

10. **Was the timing of the outcome assessment in all groups similar?**
    Timing of outcome assessment should be identical for all intervention groups and for all important outcome measurements.

11. **Did the analysis include an intention-to-treat analysis?**
    All randomized patients are reported/analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values) irrespective of noncompliance and cointerventions.

[ii] van Tulder, M et al. Updated Method Guidelines for Systematic Reviews in the Cochrane Collaboration Back Review Group. *SPINE* (2003); 28(12): 1290-1299.

Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain and Other Pain Conditions

Health Services Advisory Council

Evidence Summary

September 11, 2008

Minnesota Department of **Human Services**

Background/Context

Up to 84 percent of adults experience back pain at some point in their life,[1] and low back pain is one of the five most common reasons for physician visits in the United States.[2] Chronic low back pain (LBP), defined as pain persisting for 6 or more weeks, affects millions of Americans and accounts for substantial health care and work loss costs. Despite the many options available to treat it,

> "…there has been little consensus, either within or between specialties, on appropriate clinical evaluation and management of low back pain. Numerous studies show unexplained, large variations in the use of diagnostic tests and treatments. Despite wide variations in practice, patients seem to experience broadly similar outcomes, although costs of care can differ substantially".[3]

One treatment for chronic LBP is transcutaneous electrical nerve stimulation (TENS), which involves the use of a small battery-powered device that delivers continuous electrical impulses to peripheral nerves via surface electrodes to modify patients' perception of pain. Conductive garments are also available to distribute stimulation to large or difficult-to-reach areas. There are a number of applications of TENS used in clinical practice, which vary in terms of frequency, amplitude, pulse width, and waveform. TENS can be self-administered or applied in a clinic environment, and patient response may be highly individualized depending on stimulation settings. Adverse effects reported in trials are mostly related to skin irritation. TENS was added to existing treatments for chronic LBP more than 30 years ago, but its clinical benefit remains controversial.[4]

Treatments for chronic low back pain make up a significant proportion of Medicaid spending (particularly among people with disabilities), and a wide range of medical and pharmacological therapies are available to treat LBP. In fee-for-service Minnesota Health Care Programs (MHCP), spending on TENS totaled roughly $150,000 in CY2007, an increase of 49% from 2003-2007. The majority of TENS units and associated procedures were billed under back pain-related diagnosis codes. Given the population-wide burden of chronic LBP and the lack of clinical agreement on TENS' role in its treatment, it is worthwhile to review the evidence and ensure that MHCP coverage policy reflects it.

Summary of Evidence

As part of an evidence review on chronic low back pain interventions, the Medicaid Evidence-based Decisions (MED) Project at Oregon Health & Science University evaluated the evidence related to TENS for chronic LBP. The MED Project review forms the basis of the summary that follows, and each of the sources identified in the MED review is cited individually herein. The evidence reviewed includes three systematic reviews (one with a corresponding set of practice guidelines), and two additional sets of clinical practice guidelines.

Three recent high-quality systematic reviews heavily reference a pair of seminal trials of the efficacy of TENS for chronic LBP.[5] The conclusions of these reviews are summarized below.

- The Spine Journal published a systematic review and meta-analysis on the management of chronic LBP with TENS in 2008. The review yielded six studies, and the authors concluded that TENS appeared to have an immediate impact on pain intensity, but did not appear to have an impact on perceived disability or long-term pain. Noting the contradictory results of studies and the variation in TENS treatment protocols and follow-up periods, the authors further recommended that TENS "should probably be used as an adjunct tool for immediate to short-term pain relief, with no impact on perceived disability or long-term pain."

- A 2007 systematic review, conducted by Chou et al., was published in the Annals of Internal Medicine along with a set of American College of Physicians and American Pain Society clinical practice guidelines based on its results. Both documents address TENS individually as one of a number of non-pharmacologic therapies for LBP. The review reported mixed evidence, with one lower-quality trial finding TENS superior to placebo for chronic LBP and a larger, higher-quality trial finding no difference between TENS and sham TENS for any measured outcomes. The accompanying guidelines concluded that TENS had not been proven effective for chronic LBP and did not recommend its use.

- The Cochrane Collaboration published a systematic review on TENS for chronic LBP in 2005. Citing the same trials as the Chou et al. review, the Cochrane reviewers concluded that there was "limited and inconsistent evidence to support the use of TENS as an isolated intervention in the management of chronic LBP." Calling for larger, multi-center randomized controlled trials to further study TENS, Khadilkar et al. also raised the need to evaluate long-term TENS use given the nature of managing chronic LBP.

Two additional sets of clinical practice guidelines addressing TENS for chronic LBP were reviewed, and their recommendations are summarized below.

- In 2007 the European Federation of Neurological Societies (EFNS) published a set of guidelines on neurostimulation for neuropathic pain. Although not limited to chronic LBP, the guidelines state that it is difficult to arrive at evidence-based conclusions on TENS and that it "is possibly better than placebo…though probably worse than acupuncture-like or any other kind of electrical stimulation."

- The Institute for Clinical Systems Improvement (ICSI) guideline on adult low back pain was last updated in September of 2006. For chronic low back pain (absent sciatica), the ICSI guideline recommends a course of active rehabilitation. Citing the 1990 Deyo et al. trial,[6] the guideline does not recommend TENS for the treatment of chronic LBP.

A PubMed search uncovered no additional randomized trials on the effectiveness of TENS for low back pain in the general population published since the 2005 Cochrane review.

Conclusions and Proposed Authorization Criteria

There is limited and somewhat conflicting evidence on the effectiveness of TENS for treating chronic low back pain. Two studies were included in multiple systematic reviews: the Cheing and Hui-Chan trial that demonstrated significant pain relief measured pain during a single one hour treatment with no follow-up – a dose not commonly used clinically. The Deyo et al. trial utilized a more typical 4-week course of daily TENS therapy and found no significant benefits.[7] In the systematic reviews evaluated, the trials with positive findings measured outcomes immediately following the final TENS session; those with longer follow-up had negative findings.[8] Reflecting the weight of the available evidence, clinical practice guidelines generally do not recommend the use of TENS to treat chronic low back pain.

With a number of treatment options available for chronic low back pain with stronger evidence of long-lasting benefit (such as multidisciplinary rehabilitation and exercise with a cognitive-behavioral approach),[9] the evidence suggests that TENS should not be covered for the treatment of chronic low back pain. Evidence-based coverage criteria would restrict TENS to short-term use for patients with acute pain and chronic pain conditions (except chronic LBP) that are refractory to other treatments. Since this evidence review does not address other common indications for TENS, the policy would leave open the possibility of medically necessary TENS use for conditions beyond chronic LBP. A set of proposed authorization criteria follows.

DHS will authorize transcutaneous electrical nerve stimulation (TENS) units as medically necessary for the following indications only:

- For acute (non-malignant) post-operative or post-traumatic pain, TENS units will be approved for rental for a period of no more than 60 days following surgery or injury. If the device is required for a longer period, the criteria for chronic pain apply.

  DOCUMENTATION REQUIRED: Written description of the patient's operation or trauma and the need for TENS.

- For chronic pain conditions that are refractory to other patient-appropriate methods of treatment, TENS units will be approved for purchase or capped rental. TENS is *not* covered for the treatment of chronic low back pain (defined as low back pain persisting for six weeks or more).

  DOCUMENTATION REQUIRED: Written description of prior therapies attempted and patient's response.

DHS will authorize form-fitting conductive garments prescribed by a physician for the medically necessary TENS indications listed above if any of the following criteria are met:

- The area receiving stimulation is inaccessible with the use of conventional electrodes, tapes, and lead wires.

- The area receiving stimulation is so large or the sites so numerous that conventional electrodes, tapes, and lead wires are not practical.

- The patient has a skin condition or other medical condition that prevents the application of conventional electrodes, tapes, and lead wires.

  DOCUMENTATION REQUIRED: Written description of the patient's need for a conductive garment, addressing one or more of the criteria above.

Proposed Codes

CPT

64550 - Application of surface (transcutaneous) neurostimulator

HCPCS

A4595 - Electrical stimulator supplies, 2 lead, per month
A4630 - Replacement batteries, medically necessary, transcutaneous electrical nerve stimulator, owned by patient
E0720 - Transcutaneous electrical nerve stimulation (TENS) device, two lead, localized stimulation
E0730 - Transcutaneous electrical nerve stimulation (TENS) device, four or more leads, for multiple nerve stimulation
E0731 - Form-fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patients skin by layers of fabric)

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[4] Khadilkar A et al. Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low-Back Pain. *Cochrane Database of Systematic Reviews* (2005);3:CD003008.

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and

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[6] Deyo RA et al. A Controlled Trial of Transcutaneous Electrical Nerve Stimulation (TENS) and Exercise for Chronic Low Back Pain. *The New England Journal of Medicine* (1990);322(23):1627-34.

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Oregon Health & Science University (OHSU) Center for Evidence-Based Policy. *Rapid Review: Interventions for Chronic Low Back Pain*. Portland, OR. (2008).

Poitras S and Brosseau L. Evidence-Informed Management of Chronic Low Back Pain with Transcutaneous Electrical Nerve Stimulation, Inferential Current, Electrical Muscle Stimulation, Ultrasound, and Thermotherapy. *The Spine Journal* (2008);8(1):226-33. WEB LINK TO ABSTRACT

Table 1: Evidence Consulted

Organization/Title/Year **Method to Analyze Evidence**	**Scope**	**Objectives**	**Methods to Make Recommendations / Conclusions**
Cheing GLY and Hui-Chan CWY: *Archives of Physical Medicine and Rehabilitation* 1999 (Journal Article) **Randomized Trial**	Evaluation Treatment	To investigate to what extent a single 60-minute session of TENS would modify chronic clinical pain, acute experimental pain, and the flexion reflex evoked in chronic low back pain patients.	Study Results
Chou R and Huffman LH: American College of Physicians and the American Pain Society: *Annals of Internal Medicine* 2007 (Clinical Specialty Organizations, Journal Article) **Systematic Review**	Evaluation Treatment	To assess benefits and harms of acupuncture, back schools, psychological therapies, exercise therapy, functional restoration, interdisciplinary therapy, massage, physical therapies (including TENS), spinal manipulation, and yoga for acute or chronic low back pain (with or without leg pain).	Expert Consensus
Chou R et al: American College of Physicians and the American Pain Society: *Annals of Internal Medicine* 2007 (Clinical Specialty Organizations, Journal Article) **Systematic Review**	Evaluation Diagnosis Treatment	To present the available evidence for evaluation and management of acute and chronic low back pain in primary care settings.	Expert Consensus
Cruccu G et al. European Federation of Neurological Societies (EFNS): *European Journal of Neurology* 2007 (Clinical Specialty Organizations, Journal Article) **Review of Published Meta-Analyses** **Systematic Review**	Management Treatment	To provide the neurologist with evidence-based recommendations that may help to determine when a patient with neuropathic pain should try a neurostimulation procedure.	Expert Consensus
Deyo RA et al: *The New England Journal of Medicine* 1990 (Journal Article) **Randomized Trial**	Evaluation Treatment	To examine the effectiveness of TENS, a program of stretching exercises, or a combination of both for chronic low back pain.	Study Results

Organization/Title/Year **Method to Analyze Evidence**	**Scope**	**Objectives**	**Methods to Make Recommendations / Conclusions**
Institute for Clinical Systems Improvement 2006 (Private Non-Profit Organization)	Diagnosis Evaluation Management Treatment	To increase the use of the recommended conservative approach as first-line treatment…for patients with low back pain. To reduce unnecessary imaging studies in patients with acute low back pain. To increase the appropriate assessment of patients with chronic low back pain. To increase the use of appropriate outcome tools.	
Khadilkar A et al: *Cochrane Database of Systematic Reviews* 2005 (Cochrane Database of Systematic Reviews) **Systematic Review**	Evaluation Treatment	To determine the effectiveness of TENS in the management of chronic low back pain.	Expert Opinion
OHSU Center for Evidence-Based Policy: *Rapid Review: Interventions for Chronic Low Back Pain*. 2008 *(Membership-Based Medicaid Research Organization)* **Systematic Review**	Diagnosis Evaluation Treatment	To conduct an overview of the existing research evidence on the effectiveness and safety of a range of interventions for the treatment of chronic low back pain of non-malignant origin.	Expert Opinion
Poitras S and Brousseau L: *The Spine Journal* 2008 (Journal Article) **Systematic Review** **Meta-Analysis**	Evaluation Management Treatment	To summarize the best available evidence for a particular intervention and make this information accessible to non-experts.	Expert Opinion

APPENDIX A:
HSAC Process for Summarizing Evidence

Background: HSAC, in conjunction with the DHS Medical Director, is charged with advising the Department on clinical issues to inform decision-making on coverage and benefit policy. Where applicable, DHS produces summaries of existing clinical evidence to ensure that these decisions are based on the most up-to-date and reliable clinical evidence as well as the expertise of the Council's members.

Sources: The key sources used to gather evidence is gathered are summarized below:

- **Medicaid-Specific Collaborations:** Two key organizational collaborations provide a starting point for the evaluation of topics, helping to frame clinical questions and serving as channels for consultation with other states' programs in making evidence-based coverage decisions.
    - Medicaid Evidence-Based Decisions (MED) Project – A collaboration of state Medicaid programs housed at the Center for Evidence-Based Policy at Oregon Health & Science University. MED Project creates reports and recommendations based upon clinical evidence, provides staff support and facilitates knowledge sharing between states.
    - AHRQ/AcademyHealth Medicaid Medical Directors' Learning Network – A forum for the sharing of research and experience among medical directors in state Medicaid programs across the country.
- **Keyword Searches:** Topical keyword searches are then performed, searching for clinical guidelines and relevant peer-reviewed articles using the following sources:
    - AHRQ National Guidelines Clearinghouse – A clearinghouse of recommended guidelines from medical specialty societies, private non-profit organizations, and evidence-based practice centers.
    - The Cochrane Library – An international database of clinical practice guidelines. (Access to full-text resources is somewhat limited currently.)
    - PubMed and Medline – Medical/health sciences bibliographic databases.
- **Resources Accessed Directly:** Other sources are routinely accessed directly in search of clinical guidelines and peer-reviewed articles:
    - AHRQ Evidence-Based Program – A repository of rigorous clinical reports from grant-funded evidence-based practice centers across the U.S. and Canada.
    - Institute for Clinical Systems Improvement (ICSI) – A locally-based, nationally recognized collaboration of health care organizations that identifies best clinical practices and facilitates their implementation.
    - Technology Assessments:
        - Blue Cross and Blue Shield Association Technology Evaluation Center
        - ECRI Institute (Access provided through the MED Project)
        - ICSI

Process: After information is gathered and reviewed, sources are chosen with a preference for clinical practice guidelines (from professional organizations or independent non-profits), meta-analyses and systematic reviews, supplemented by quality peer-reviewed primary articles. Preference is also given to the most up-to-date evidence available. Summary documents are then created, providing brief background and context for the clinical issue, the amount, quality, and reliability of the evidence, and proposed action to be taken based upon that evidence. These documents are reviewed internally among DHS staff (including physicians) before coming before HSAC. HSAC uses these summary documents as a starting point for discussion around the issue in question, drawing upon their assessment of the evidence and their clinical expertise to advise DHS.

APPENDIX B:
Principles for Assessing the Quality of Evidence

AMSTAR (Assessment of Multiple Systematic Reviews)[i]

AMSTAR is a measurement tool created to assess the methodological quality of systematic reviews. Each of the questions below is answered with one of the following:

_ Yes
_ No
_ Can't answer
_ Not applicable

1. Was an 'a priori' design provided?
The research question and inclusion criteria should be established before the conduct of the review.

2. Was there duplicate study selection and data extraction?
There should be at least two independent data extractors and a consensus procedure for disagreements should be in place.

3. Was a comprehensive literature search performed?
At least two electronic sources should be searched. The report must include years and databases used (e.g. Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated and where feasible the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found.

4. Was the status of publication (i.e. grey literature) used as an inclusion criterion?
The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc.

5. Was a list of studies (included and excluded) provided?
A list of included and excluded studies should be provided.

6. Were the characteristics of the included studies provided?
In an aggregated form such as a table, data from the original studies should be provided on the participants, interventions and outcomes. The ranges of characteristics in all the studies analyzed e.g. age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported.

7. Was the scientific quality of the included studies assessed and documented?
'A priori' methods of assessment should be provided (e.g., for effectiveness studies if the author(s) chose to include only randomized, double-blind, placebo controlled studies, or allocation concealment as inclusion criteria); for other types of studies alternative items will be relevant.

8. Was the scientific quality of the included studies used appropriately in formulating conclusions?
The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations.

9. Were the methods used to combine the findings of studies appropriate?
For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e. Chisquared test for homogeneity, I2). If heterogeneity exists a random effects model should be used and/or the clinical appropriateness of combining should be taken into consideration (i.e. is it sensible to combine?).

10. Was the likelihood of publication bias assessed?
An assessment of publication bias should include a combination of graphical aids (e.g., funnel plot, other available tests) and/or statistical tests (e.g., Egger regression test).

11. Was the conflict of interest stated?
Potential sources of support should be clearly acknowledged in both the systematic review and the included studies.

Cochrane Collaboration: Criteria List for the Methodological Quality Assessment of Individual Studies[ii]

The Cochrane criteria assess the quality and internal validity of individual trials. Each of the questions below is answered with one of the following:

_ Yes
_ No
_ Don't Know

1. **Was the method of randomization adequate?**
   A random (unpredictable) assignment sequence. Examples of adequate methods are computer generated random number table and use of sealed opaque envelopes. Methods of allocation using date of birth, date of admission, hospital numbers, or alternation should not be regarded as appropriate.

2. **Was the treatment allocation concealed?**
   Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient.

3. **Were the groups similar at baseline regarding the most important prognostic indicators?**
   In order to receive a "yes", groups have to be similar at baseline regarding demographic factors, duration and severity of complaints, percentage of patients with neurological symptoms, and value of the main outcome measure(s).

4. **Was the patient blinded to the intervention?**
   The reviewer determines if enough information about the blinding is given in order to score a "yes".

5. **Was the care provider blinded to the intervention?**
   The reviewer determines if enough information about the blinding is given in order to score a "yes".

6. **Was the outcome assessor blinded to the intervention?**
   The reviewer determines if enough information about the blinding is given in order to score a "yes".

7. **Were cointerventions avoided or similar?**
   Cointerventions should either be avoided in the trial design or similar between the index and control groups.

8. **Was the compliance acceptable in all groups?**
   The reviewer determines if the if the compliance to the interventions is acceptable, based on the reported intensity, duration, number and frequency of sessions for both the index intervention and control intervention(s).

9. **Was the drop-out rate described and acceptable?**
   The number of participants who were included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and drop-outs does not exceed 20% for short-term follow-up and 30% for long-term follow-up and does not lead to substantial bias a "yes" is scored. (N.B. these percentages are arbitrary, not supported by literature.)

10. **Was the timing of the outcome assessment in all groups similar?**
    Timing of outcome assessment should be identical for all intervention groups and for all important outcome measurements.

11. **Did the analysis include an intention-to-treat analysis?**
    All randomized patients are reported/analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values) irrespective of noncompliance and cointerventions.

[ii] van Tulder M et al. Updated Method Guidelines for Systematic Reviews in the Cochrane Collaboration Back Review Group. *SPINE* (2003);28(12):1290-9.

Virtual Colonoscopy, CT Colonography

Health Services Advisory Council

Evidence Summary

February 14, 2008

Minnesota Department of **Human Services**

Background/Context

In the United States, colorectal cancer is the second leading cause of cancer death.[1,2] In Minnesota, more persons die of colon and rectal cancer (CRC) than either breast or prostate cancer, but less than two-thirds of Minnesotans ages 50 and older report being screened as recommended.[3] According to the American Cancer Society (ACS), in 2007 an estimated 153,760 new cases of colorectal cancer will be diagnosed and an estimated 79,130 individuals will die from the disease. In Minnesota, the incidence rate of CRC decreased by 17% and the mortality rate by 25% between 1988 and 2003. However, American Indian men in Minnesota have an 80% higher risk of being diagnosed with CRC than non-Hispanic white men. Also CRC incidence rates were higher in Southwest, West Central and Northwest Minnesota which may reflect differences in proportion of the population who are screened as well as differences in underlying risk of developing disease. Only 40% of CRC cases in Minnesota are diagnosed at an early stage when treatment is more successful.[4]

As a disease, colorectal cancer is very sensitive to screening. CRC develops from polyps originating in the epithelial cells that line the inside of the colon or rectum. About 10% of all colonic polyps are cancer-causing and typically the progression to carcinoma occurs over the course of 10 years or longer. Epidemiological data have suggested that removal of adenomas with colonoscopy reduces the incidence of colorectal cancer by up to 90%.[5]

Virtual colonoscopy has been considered as an alternative technique to conventional colonoscopy and double contrast barium enema for colon cancer screening. CT colonography, also known as virtual colonoscopy, is a non-invasive imaging technique of the colon utilizing multi-slice thin section computed tomography to generate two-dimensional images of the colon. A three-dimensional intra-luminal image is then created through reformatting of the images off-line. For colorectal cancer, it can be a tool for screening asymptomatic individuals or a diagnostic tool for symptomatic individuals. Virtual colonography, like colonoscopy, requires a full bowel preparation and gas insufflation of the intestine. However, it can be performed with less sedation, decreased risk of bowel perforation, and less patient time for the procedure when compared with colonoscopy. The most common adverse events reported with virtual colonography are the diagnoses of extracolonic findings. Improved patient compliance with routine CRC screening and the consequent discovery of earlier stage cancer are the most common justifications given in support of virtual colonography. In the fee-for-service Minnesota Health Care Programs (MHCP), the codes for virtual colonography are currently not covered. The procedure may be occurring and billed through undefined codes. However, given the expected increase in the utilization of this procedure system-wide, it is beneficial to examine the evidence of its efficacy in relation to patient outcomes and established diagnostic alternatives.

Summary of Evidence

The evidence reviewed for this summary includes two meta-analyses, one systematic review, one large case control study, four clinical practice guidelines and three plan coverage determinations. An issue identified in the evidence reviews is the finding of variable sensitivity with consistently high specificity. Lack of standardized technical guidelines has been identified as the source of the heterogeneity of the sensitivity results.

When a technology is used as a tool for screening an asymptomatic population for disease, then sensitivity (finding all persons with disease) should be consistently higher than specificity (all lesions found are disease). None of the documents reviewed recommend CT colonography as a screening tool for an asymptomatic population. However, there are situations where the evidence supports the use of virtual colonography as a tool for diagnosing CRC.

The two meta-analyses reviewed the performance of CT colonography compared to colonoscopy or surgery considered to be the screening and diagnostic gold standard technologies.

- A 2003 meta-analysis by American Roentgen Ray Society "reported the accuracy of CT colonography compared with conventional colonoscopy for detecting colorectal polyps." The scope of the analysis was limited to prospective studies with entire colon evaluation by CT colonography and reference standard of full conventional colonoscopy along with blinded review. Bowel prep was standardized and CT scanner specifications controlled. Based on 14 clinical trials, involving 1,324 patients and 1,411 polyps found a pooled sensitivity of:

  1. polyps 10mm or larger 0.88 [95% CI 0.84-0.93]
  2. polyps 6-9mm 0.84 [95% CI 0.80-0.89]
  3. polyps 5mm or smaller 0.43 [95% CI 0.39-0.47]

  The pooled specificity for polyps larger than 10mm was 0.95 [95% CI 0.94-0.97]. It concluded that while the performance of CT colonography in identifying small polyps was poor that clinically these are the least likely to be associated with cancer. As a technology, it has a low rate of false-positives, so the lesions identified requiring subsequent colonoscopy and/or surgery are likely to be disease causing polyps.

- A 2005 meta-analysis by American College of Physicians reviewed 33 studies involving 6,393 patients. Prospective studies involving full bowel preparation with colonoscopy or surgery as the gold standard were selected. Additional technical requirements for the scanner and the collated images viewed for interpretation along with blinded review were part of the inclusion criteria. Sensitivities and specificities were weighted by sample size. Identifying the source of the variation of study results was explored using stratified analysis and meta-regression. Like the previous meta-analysis, sensitivities improved with polyp size. Wide confidence intervals with smaller polyps indicate heterogeneous results. Specificity was fairly consistent across polyp size with narrow confidence intervals, indicating homogeneous study results. The technical characteristics of CT colonography identified as influencing the variation in sensitivity results were the width of collimation, type of detector and mode of imaging.

- ECRI conducted a systematic review published November 2007. The review included 24 studies with 8,145 patients. Conclusions of the analysis:
  1. Moderate evidence support for CT colonography for ruling out CRC in asymptomatic patients.
  2. Moderate evidence support for ruling out clinically important asymptomatic polyps in patients.
  3. Moderate evidence support for identifying clinically important polyps in diagnosing symptomatic patients.
  4. Sixteen slice CT scanners provide sufficient quality images but 64 slice scanners do a better job of reducing artifact due to peristalsis.
  5. Recommends minimum training and competency assessment for image interpretation by gastroenterologists and radiologists.

6. No studies on long-term survival or quality of life were identified.

The four clinical practice guidelines for colorectal cancer screening reviewed conclude the following:

- American Cancer Society (ACS) 2006 Guideline for early cancer detection recommends screening asymptomatic people 50 years and older (see Appendix A for screening guidelines). ACS regards CT colonography as a non-recommended test or procedure due to insufficient evidence. It did not consider patients with incomplete or medically contraindicated colonoscopy.

- The American Society of Colon and Rectal Surgeons (ASCRS) 2006 practice parameters does not consider CT colonography appropriate for widespread screening in clinical practice.

- American College of Radiology (ACR) 2006 expert panel on imaging in CRC screening 2006 considers CT colonography to be an appropriate screening examination for individuals of average-, moderate-, or high-risk individuals after incomplete colonoscopy, as a surveillance exam in patients with prior colonic neoplasm, for diagnosing patients symptomatic for CRC, and for patients on anticoagulant medication who require colonoscopy.

- ICSI's 2006 CRC screening guideline concludes: "CT colonography seems to be a reasonable colonic imaging examination in the following clinical situations: after incomplete screening or diagnostic colonoscopy; in anticoagulated patients who cannot safely discontinue anticoagulation therapy, and in patients who refuse colonoscopy and understand that their insurance may or may not cover the cost of the CT."

The large case control study was conducted at a single institution (the University of Wisconsin Medical School, Madison) and published in NEJM in 2007. Individuals were referred by a physician for CT colonography, completed the procedure, results were immediately determined, and a follow on colonoscopy was conducted. 3,120 adults received primary CT colonography. Open access determined those adults receiving colonoscopy with subsequent CT colonography and 3,163 adults entered the protocol through this mechanism. Both were healthy screening cohorts. The study limitations include potential selection bias influencing the study population and the use of a single institution. Findings included similar detection rates of advanced neoplasias for both screening techniques. 7.9% of CT colonographies resulted in subsequent colonoscopies for polypectomy.

The three plan coverage determinations reviewed include AIM, BC/BS of Minnesota and Medica. All consider the use of CT colonography as a screening tool for asymptomatic patients with or without risk factors to be a non-covered technique. Coverage of CT colonography for diagnostic purposes is indicated following incomplete colonoscopy, contraindicated colonoscopy due to coagulopathy, anticoagulation, increased risk of perforation, or known colonic obstruction. Increased risk from sedation and excessive risk for endocarditis are indications stated but not uniformly agreed upon.

Policy Option: Proposed Authorization Criteria

Authorization is required for virtual colonoscopy/CT colonography, and MHCP will approve these procedures for screening and diagnosis per the criteria below in cases of incomplete or contraindicated optical colonoscopy. Screening scans may occur every five years. 64 slice (or greater) scanners must be used in all cases. Approved indications are:

- Coagulopathy
- Anticoagulation (optical colonoscopy contraindicated due to increased patient risk with discontinuation of anticoagulant medication) (Anticoagulation is defined by an INR of 1.5 or greater)
- Incomplete optical colonoscopy of the entire colon due to obstructing neoplasm, spasm, redundant colon, scarring or altered anatomy from previous surgery, stricture or extrinsic compression

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[5] Winawer SJ, Zauber AG, Ho MN, et al. The National Polyp Study Workgroup. Prevention of colorectal cancer by colonoscopic polypectomy. *New England Journal of Medicine.* 329(1993):1977-81.

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Table 1: Evidence Consulted

Organization/Title/Year **Method to Analyze Evidence**	**Scope**	**Objectives**	**Methods to Make Recommendations / Conclusions**
American Cancer Society Guidelines for Early Detection of Cancer 2006 **Systematic Review**	Screening	To summarize recommendations for early detection of cancer, update guidelines, address issues relevant to screening and summarize current data on screening rates	Expert Consensus
American College of Radiology 2006 **Meta-Analyses** **Systematic Review**	Diagnosis Screening	To evaluate the appropriateness of initial radiologic examinations for colorectal cancer screening	Expert Consensus
American Society for Gastrointestinal Endoscopy 2006 **Meta-Analyses**	Prevention Risk Assessment Screening	To provide guidelines for colorectal cancer screening and surveillance in average- and high-risk individuals	Expert Consensus
The Institute for Clinical Systems Improvement (ICSI): Colorectal cancer screening 2006 **Systematic Review**	Evaluation Prevention Risk Assessment Screening	To increase colorectal cancer screening, follow-up of positive tests and reduction of unproductive screening processes	Expert Consensus
University of Michigan Health System. Adult preventive health care: cancer screening 2004 **Systematic Review**	Prevention Risk Assessment Screening	To implement an evidenced-based strategy for colorectal cancer screening	Expert Consensus
U.S. Multisociety Task Force on Colorectal Cancer 2003 **Systematic Review**	Screening	To incorporate updated evidence into clinical practice recommendations To summarize new developments and how they impact practice	Expert Consensus
U.S. Preventive Services Task Force 2002 **Systematic Review**	Screening	To make recommendations on screening for colorectal cancer	Expert Consensus

APPENDIX A:
American Cancer Society Screening Guidelines for the Early Detection of Cancer of the Colon and Rectum in Asymptomatic People

Beginning at age 50, both men and women should follow 1 of these 5 testing schedules:

- yearly fecal occult blood test (FOBT)* or fecal immunochemical test (FIT)
- flexible sigmoidoscopy every 5 years
- yearly FOBT* or FIT, plus flexible sigmoidoscopy every 5 years**
- double-contrast barium enema every 5 years
- colonoscopy every 10 years

*For FOBT, the take-home multiple sample method should be used. **The combination of yearly FOBT or FIT flexible sigmoidoscopy every 5 years is preferred over either of these options alone.

All positive tests should be followed up with colonoscopy.

US Multi-society Task Force on Colorectal Cancer: Updated Guidelines for Screening and Surveillance

Screening Modifications:

- Rehydration is no longer recommended for fecal occult blood tests
- Use colonoscopy, instead of barium enema, for diagnostic evaluation of patients with positive findings on other screening tests
- Screening interval for double-contrast barium enema has been shortened from every 10 years to every 5 years
- More detailed recommendations are provided for genetic testing in patients with family members who carry genetic mutations.
- Screening colonoscopy is recommended for people with a first-degree relative who had colorectal neoplasia that was diagnosed before age 60, or with 2 or more affected first-degree relatives

Codes	Number	Description
CPT	0066T	CT colonography (ie, virtual colonoscopy); screening
	0067T	CT colonography (ie, virtual colonoscopy); diagnostic
HCPCS	No code	

APPENDIX B:
HSAC Process for Summarizing Evidence

Background: HSAC, in conjunction with the DHS Medical Director, is charged with advising the Department on clinical issues to inform decision-making on coverage and benefit policy. Where applicable, DHS produces summaries of existing clinical evidence to ensure that these decisions are based on the most up-to-date and reliable clinical evidence as well as the expertise of the Council's members.

Sources: The key sources used to gather evidence is gathered are summarized below:

- **Medicaid-Specific Collaborations:** Two key organizational collaborations provide a starting point for the evaluation of topics, helping to frame clinical questions and serving as channels for consultation with other states' programs in making evidence-based coverage decisions.
    - Medicaid Evidence-Based Decisions (MED) Project – A collaboration of state Medicaid programs housed at the Center for Evidence-Based Policy at Oregon Health & Science University. MED Project creates reports and recommendations based upon clinical evidence, provides staff support and facilitates knowledge sharing between states.
    - AHRQ/AcademyHealth Medicaid Medical Directors' Learning Network – A forum for the sharing of research and experience among medical directors in state Medicaid programs across the country.

- **Keyword Searches:** Topical keyword searches are then performed, searching for clinical guidelines and relevant peer-reviewed articles using the following sources:
    - AHRQ National Guidelines Clearinghouse – A clearinghouse of recommended guidelines from medical specialty societies, private non-profit organizations, and evidence-based practice centers.
    - The Cochrane Library – An international database of clinical practice guidelines. (Access to full-text resources is somewhat limited currently.)
    - Medline (Full-Text Only) – The National Library of Medicine's bibliographic database and search engine.

- **Resources Accessed Directly:** Other sources are routinely accessed directly in search of clinical guidelines and peer-reviewed articles:
    - AHRQ Evidence-Based Program – A repository of rigorous clinical reports from grant-funded evidence-based practice centers across the U.S. and Canada.
    - Institute for Clinical Systems Improvement (ICSI) – A locally-based, nationally recognized collaboration of health care organizations that identifies best clinical practices and facilitates their implementation.
    - Journal Subscriptions:
        - New England Journal of Medicine
        - Health Affairs
    - Technology Assessments:
        - Blue Cross and Blue Shield Association Technology Evaluation Center
        - ECRI (Access provided through the MED Project)
        - ICSI

Process: After information is gathered and reviewed, sources are chosen with a preference for clinical practice guidelines (from professional organizations or independent non-profits), meta-analyses and systematic reviews, supplemented by quality peer-reviewed primary articles. Preference is also given to the most up-to-date evidence available. Summary documents are then created, providing brief background and context for the clinical issue, the amount, quality, and reliability of the evidence, and proposed action to be taken based upon that evidence. These documents are reviewed internally among DHS staff (including physicians) before coming before HSAC. HSAC uses these summary documents as a starting point for discussion around the issue in question, drawing upon their assessment of the evidence and their clinical expertise to advise DHS.