Health Technology Assessment Program

Selected Technologies 2017

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No public comments were received on the 2017 prospective topics.

STATE OF WASHINGTON
HEALTH CARE AUTHORITY
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June 8, 2017

To whom it may concern:

SUBJECT: Health Technology Assessment Topic Selection, 2017

As the Director of the Health Care Authority and per the Health Technology Assessment law (70.14 RCW), I select technologies for review by the program in consultation with other agencies and the Health Technology Clinical Committee. Technologies are selected when there are concerns about safety, efficacy or value (cost-effectiveness), when state expenditures are or could be high, and there is adequate evidence to conduct a review. Technologies are selected for re-review when new evidence is available that could change a previous determination. In addition, anyone may petition for a technology review.

For the current selection cycle, I have reviewed the proposed topics as well as the comments received from the interested individuals and groups who responded in the first comment period (May 2 to May 16, 2017). Based on the information provided by the Health Technology Assessment program, and the recommendations from staff in the Health Care Authority, Department of Labor and Industries, and Department of Corrections, I have selected the following technologies for review:

	Technology	Safety	Efficacy	Cost
1	**Surgical interventions for unilateral, single-level nerve root compression with radiculopathy**	**Med**	**Med**	**High**
	Policy context/ reason for selection: Surgical treatments for back pain can include procedures to decompress or alleviate pressure on important nerves in the spine. Some of these procedures including laminectomies and laminotomies offer less invasive options for treatment. Back pain is one of the most common conditions treated with a high burden for patients. The topic is proposed to determine the safety, efficacy and value of interventions for treatment of single-level nerve root compression.			
2	**Extremity ultrasound**	**Low**	**High**	**Med/High**
	Policy context/ reason for selection: Extremity ultrasound is a non-invasive imaging technique that employs high-frequency sound waves to evaluate the conditions in the arms and legs. Imaging of extremity soft tissues may be a useful additional diagnostic tool and may help evaluate healing progress. The topic identified based on uncertainties related to safety, efficacy and value of extremity ultrasound.			

	Technology	Safety	Efficacy	Cost
3	**Genomic micro-array and whole exome sequencing**	**Med**	**High**	**High**
	Policy context/ reason for selection: Genomic micro-array and whole exome sequencing tests may identify, or confirm the presence of chromosome abnormalities. Whether results from genetic sequencing can improve diagnosis, treatment decisions and health outcomes in some situations remains uncertain.			
4	**Genetic testing or molecular pathology testing of cancers**	**Med**	**Med/High**	**High**
	Policy context/ reason for selection: Genetic and molecular pathology tests are available for breast, prostate, and colon cancers and for myeloma. These analyses may help identify the likelihood that a cancer reappears and/or whether a specific cancer therapy is worth the risk. As new tests emerge in the marketplace, questions remain regarding test safety, sensitivity and specificity.			
5	**Pharmacogenomic testing: Selected conditions**	**Low**	**High**	**Med/High**
	Policy context/ reason for selection: New laboratory tests and computer based predictive algorithms are available to assess an individual patient's potential metabolic response to various drugs. Potential benefits include better application of the drugs or chemotherapy choices that will work for a specific individual. Concerns relate to whether specific tests result in improved treatment decisions and health outcomes, as well as rapid emergence and uptake of pharmacogenomic tests generally. Concerns are considered low for the safety of these tests, high for efficacy and medium/high for cost-effectiveness.			

[1] Link to ***primary criteria ranking***.

Additionally, I have selected *Continuous glucose monitoring* for re-review based on the newly available published evidence.

Upon publication of the selected list of technologies, a 30-day comment period will begin whereby any interested person or group may provide information relevant to review of these topics. Health Technology Assessment will begin work to review these technologies following this comment period.

Should you have any questions or concerns, please contact Josh Morse, Health Technology Assessment Program Director by telephone at 360-725-0839 or via email at Josh.morse@hca.wa.gov.

Sincerely,

[redacted]

Dorothy F. Teeter, MHA
Director

Washington State Health Care Authority

Technologies selected

	Technology	Safety	Efficacy	Cost
1	**Surgical interventions for unilateral, single-level nerve root compression with radiculopathy**	**Med**	**Med**	**High**
	Policy context/ reason for selection: Surgical treatments for back pain can include procedures to decompress or alleviate pressure on important nerves in the spine. Some of these procedures including laminectomies and laminotomies offer less invasive options for treatment. Back pain is one of the most common conditions treated with a high burden for patients. The topic is proposed to determine the safety, efficacy and value of interventions for treatment of single-level nerve root compression.			
2	**Extremity ultrasound**	**Low**	**High**	**Med/High**
	Policy context/ reason for selection: Extremity ultrasound is a non-invasive imaging technique that employs high-frequency sound waves to evaluate the conditions in the arms and legs. Imaging of extremity soft tissues may be a useful additional diagnostic tool and may help evaluate healing progress. The topic identified based on uncertainties related to safety, efficacy and value of extremity ultrasound.			
3	**Genomic micro-array and whole exome sequencing**	**Med**	**High**	**High**
	Policy context/ reason for selection: Genomic micro-array and whole exome sequencing tests may identify, or confirm the presence of chromosome abnormalities. Whether results from genetic sequencing can improve diagnosis, treatment decisions and health outcomes in some situations remains uncertain.			
4	**Genetic testing or molecular pathology testing of cancers**	**Med**	**Med/High**	**High**
	Policy context/ reason for selection: Genetic and molecular pathology tests are available for breast, prostate, and colon cancers and for myeloma. These analyses may help identify the likelihood that a cancer reappears and/or whether a specific cancer therapy is worth the risk. As new tests emerge in the marketplace, questions remain regarding test safety, sensitivity and specificity.			
5	**Pharmacogenomic testing: Selected conditions**	**Low**	**High**	**Med/High**
	Policy context/ reason for selection: New laboratory tests and computer based predictive algorithms are available to assess an individual patient's potential metabolic response to various drugs. Potential benefits include better application of the drugs or chemotherapy choices that will work for a specific individual. Concerns relate to whether specific tests result in improved treatment decisions and health outcomes, as well as rapid emergence and uptake of pharmacogenomic tests generally. Concerns are considered low for the safety of these tests, high for efficacy and medium/high for cost-effectiveness.			

Technologies considered, not proposed

	Technology
1	Acupuncture
2	High frequency chest wall oscillation
3	Massage therapy
4	Non-pharmacologic treatment of urinary incontinence
5	Wearable external cardiac defibrillator
6	PET beta amyloid and tau scanning for Alzheimer's and mild cognitive impairment
7	Pharmacogenomic testing for chronic pain conditions

Technologies selected for re-review:

Technologies are considered for re-review at least once every eighteen months based on availability of new evidence that may change the decision. (Detailed criteria are included below). All technologies with determinations beyond 18 months since the final determination previously reviewed by the Health Technology Clinical Committee (HTCC) are listed below, along with information on whether they have been selected for re-review.

	Technology	Originally reviewed	Recommended for re-review
1	**Continuous glucose monitoring**	**March 2011**	**Yes**
	This topic was originally reviewed in 2011. It is proposed for re-review based on new evidence and newly expanded indications for continuous glucose monitoring (CGM). New evidence and indications are identified that support re-reviewing the evidence for continuous glucose monitoring		
2	**Spinal cord stimulation for neuropathic pain**	**August 2009**	**No**
	Signal search conducted in 2016 (attached). New information does not support re-review at this time.		
3	**Vertebroplasty, kyphoplasty, sacroplasty**	**March 2011**	**No**
	Signal search conducted in 2016 (attached). A new randomized control trial conducted in Australia was published in 2016. This topic is not identified for re-review at this time. Though a positive short term benefit was identified for pain, no functional improve was found to confirm benefit		
4	**Stereotactic radiation surgery and stereotactic body radiation therapy**	**March 2013**	**No**
	Signal search conducted in 2016 (attached). Update search findings do not appear to support a re-review at this time		

The HTA program has not received or identified new evidence to support review of the following for at least 18 months.

	HTA Decisions	Latest review/ Scan
1	Arthroscopic knee surgery	October 2008
2	Bone growth stimulators	August 2009
3	Computed tomographic angiography (CTA)	May 2009
4	Calcium scoring	May 2010
7	Knee joint replacement or knee arthroplasty	December 2010
8	Positron emission tomography (PET) scans for lymphoma	November 2011
9	Microprocessor-controlled lower limb prosthetics	March 2012
10	Osteochondral allograft / autograft transplantation	March, 2012
11	Sleep apnea diagnosis and treatment	May 2012
12	Bone morphogenetic protein (BMP)	May 2012
13	Upright / positional MRI	June 2012
14	Hip resurfacing	August 2012
15	Robotic assisted surgery	September, 2012
16	Upper endoscopy for GERD and GERD-like symptoms	September 2012
17	Virtual colonoscopy or computed tomographic colonography (CTC)	December 2012
18	Vitamin D screening and testing	March 2013
19	Hyperbaric oxygen for wound healing	May 2013
20	Cervical spinal fusion for degenerative disc disease	May 2013
21	Ablation procedures for supraventricular tachycardia	September 2013
22	Cochlear implants	September 2013
23	Discography	November 2013
24	Implantable infusion pumps	November 2013
25	Electrical neural stimulation (ENS)	November 2013
26	Hyaluronic acid / viscosupplementation	November 2013
27	Routine ultrasound for pregnancy	November 2013
28	Intensity modulated radiation therapy	November 2013
29	Carotid artery stenting	November 2013
30	Cardiac nuclear imaging	November 2013
31	Spinal cord stimulators	September 2016
32	Non-pharmacological treatments for treatment-resistant depression	March 2014

Final

	HTA Decisions	Latest review/ Scan
33	Facet neurotomy	March 2014
34	Proton beam therapy	May 2014
35	Screening and monitoring tests for osteopenia/osteoporosis	November 2014
36	Functional neuroimaging for primary degenerative dementia or mild cognitive impairment	November 2014
37	Appropriate imaging for breast cancer screening in special populations	January 2015
38	Testosterone testing	March 2015
39	Imaging for rhinosinusitis	May 2015
40	Bariatric surgery	May 2015
41	Tympanostomy tubes in children	November 2015
42	Lumbar fusion for degenerative disc disease	November 2015

Continuous Glucose Monitoring for Individuals with Type 1 or Type 2 Diabetes

Rapid Review

April 2016

Center for Evidence-based Policy
Medicaid Evidence-based Decisions Project (MED)
Oregon Health & Science University
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Overview

This report evaluates the effectiveness of continuous glucose monitoring (CGM) vs. self-monitoring of blood glucose (SMBG) for improving glycemic control and clinical outcomes in individuals with type 1 or type 2 diabetes. There is slight disagreement on what a clinically meaningful percent difference in hemoglobin A1c (HbA1c) is between intervention groups. The Food and Drug Administration (FDA) considers a -0.4% difference as clinically meaningful (Langendam et al., 2012; US Food and Drug Administration, 2008). Other experts consider a change in HbA1c of at least -0.5% as clinically meaningful (Golden et al., 2012). Most studies included in this review based their sample size calculation off of a -0.5% or greater reduction in HbA1c between intervention groups. For the purposes of interpreting HbA1c results in this report, we used the slightly more conservative mean reduction of -0.5% as clinically meaningful. We considered both statistical and clinical significance when evaluating HbA1c study results in this report. This report also provides a summary of public and private payer coverage policies for CGM devices.

Key Findings

Comparative Effectiveness of Continuous Glucose Monitoring

Adults – Type 1 Diabetes

- Two of the 4 identified RCTs demonstrated that CGM compared to SMBG statistically significantly reduced HbA1c (-0.41% and -0.53%)
- Only one study showed a clinically meaningful mean reduction in HbA1c (i.e., a reduction of at least 0.50%) in the CGM vs. SMBG group
- No identified RCTs (0 out of 4) demonstrated that CGM compared to SMBG statistically significantly reduced severe hypoglycemic events

Adults – Type 2 Diabetes

- Two out of the 5 identified RCTs demonstrated that CGM compared to SMBG statistically significantly reduced HbA1c (-0.60% and -0.70%); both of these mean reductions were clinically meaningful
- One study demonstrated that CGM + physical activity counselling + diabetes education (including SMBG) compared to diabetes education (including SMBG) alone statistically and clinically significantly reduced HbA1c (-0.84%)
- No identified RCTs (0 out of 5) demonstrated that CGM compared to SMBG statistically significantly reduced severe hypoglycemic events

Adults – Mixed Population Type 1 and Type 2

- No identified RCTs (0 out of 3) demonstrated that CGM compared to SMBG statistically significantly reduced HbA1c or severe hypoglycemic events

Children and Adolescents – Type 1 Diabetes

- One out of 5 identified RCTs demonstrated that CGM compared to SMBG statistically significantly reduced HbA1c (-0.46%)
- One of the 5 identified RCTs demonstrated that CGM compared to SMBG statistically significantly reduced severe hypoglycemic events (0/76 vs. 4/78 events per group)

Adults, Children, and Adolescents – Mixed Population Type 1

- Six out of 7 identified RCTs demonstrated that CGM compared to SMBG statistically significantly reduced HbA1c (range: -0.27% to -0.60%)
- Only one study showed a showed a clinically meaningful mean reduction in HbA1c in the CGM vs. SMBG group (-0.60%)
- One of the 7 identified RCTs demonstrated that CGM compared to SMBG statistically significantly reduced severe hypoglycemic events (3/72 vs. 11/66 events per group)

Pregnant Women

- One out of 4 identified RCTs demonstrated that CGM compared to SMBG statistically significantly reduced HbA1c (-0.60%)
- One out of 4 RCTs identified demonstrated marginally statistically significant improvements in birth weight and 64% reduced odds of fetal macrosomia
- No identified RCTs (0 out of 4) demonstrated that CGM compared to SMBG statistically significantly reduced severe hypoglycemic events or reported other serious adverse events

Federal, State Medicaid, and Private Payer Coverage Policies

- Most state and private payers cover CGM for type 1 diabetes only
- Most state and private payer policies specify that beneficiaries must demonstrate:
    - Recurrent and/or severe hypoglycemia
    - Hypoglycemia unawareness (or unexplained fluctuations in blood glucose)
- Fewer state and private payer policies require beneficiaries to demonstrate:
    - Frequent self-monitoring and appropriate modifications to insulin regime
    - Diabetic ketoacidosis
- The following technologies were not covered:
    - Closed-loop systems (Washington Medicaid)
    - Artificial pancreas (Atena)
    - Remote glucose monitoring and related technology (Cigna and UnitedHealthcare)

Background

Diabetes is a metabolic disorder of the endocrine system that results when either the pancreas fails to produce sufficient insulin or the body does not use the insulin effectively, or both. The result is high blood glucose levels or hyperglycemia in the patient. Two common forms of this chronic condition are type 1, insulin dependent diabetes and type 2, non-insulin dependent diabetes. Management of diabetes may involve multiple daily doses of insulin, oral medication, blood glucose monitoring, and diet and exercise programs. Long-term complications of diabetes include microvascular complications (e.g., retinopathy or blindness, nephropathy, and neuropathy) and macrovascular complications (e.g., coronary heart disease, cerebrovascular disease, and peripheral arterial disease) (Yeh et al., 2012).

Individuals are diagnosed with diabetes when they have an HbA1c level of ≥6.5%. A second HbA1c is recommended for individuals who do not have a clear clinical diagnosis (e.g., the patient has classic symptoms of hyperglycemia or hyperglycemic crisis and a random plasma glucose ≥200 mg/dL [11.1 mmol/L]. The American Diabetes Association recommends the following HbA1c goals for each population of interest in this report (American Diabetes Association, 2016)

- **Non-pregnant adults**: <7% (53 mmol/mol)
- **Adolescents and children**: <7.5% (58 mmol/mol)
- **Pregnant women**: 6 to 6.5% (42-48 fmmol/mol) early on in the pregnancy and <6% (42 mmol/mol) as the pregnancy progresses if this can be achieved without significant hypoglycemia; target <7% (53 mmol/mol).

Along with HbA1c, SMBG is an important tool for maintaining good glycemic control. Individuals perform SMBG by securing a sample of blood through a finger prick and submitting the sample to a glucose meter. Most individuals on intensive insulin regimes (multiple daily injections [MDI] of basal and prandial insulin 3 to 4 times daily or insulin pump therapy) require testing their blood glucose 6-10 times daily. It is unclear whether SMBG alone helps maintain good glycemic control for individuals not on intensive insulin regimes. This includes individuals with type-2 diabetes using only basal insulin or oral agents (American Diabetes Association, 2016). Although SMBG provides an accurate measure of blood glucose levels, its intermittent nature means marked fluctuations in blood glucose can be missed. Continuous glucose monitoring systems are designed to provide continuous information about glucose levels to assist patients and physicians in maintaining glycemic control (Hayes, 2010).

Technology Description

Continuous glucose monitoring systems are minimally invasive or noninvasive devices that measure glucose levels in interstitial fluid. They usually consist of three parts: a sensor, transmitter, and monitor. Most sensors are inserted into the abdomen and can continuously measure glucose for 3 to 7 days. The transmitter sends information about glucose levels via

radio waves from the sensor to a pager-like wireless monitor. Most CGM systems also include trend and out-of-range alarms that warn patients of approaching hyperglycemia or hypoglycemia (Hayes, 2015). Two types of CGM systems exist: retrospective systems record glucose measurements for later review in a doctor's office to help with glycemic control planning; and real-time CGM systems (rt-CGM) that provide actual glucose measurements on a display every 1 to 10 minutes. Use of CGM does not replace standard SMBG, but is used to supplement the information gained from those tests (Golden et al., 2012; Hayes, 2010; Little, Leof, & Kriz, 2013). Table 1 provides brief descriptions of each diabetes management technology.

Table 1. Diabetes Management Technologies and Descriptions

Diabetes Management Technology	Description
Multiple daily injections (MDI)	Greater than or equal to three pre-meal insulin injections per day, administered by the patient via single-use syringes
Continuous subcutaneous insulin infusion (also known as an insulin pump) (CSII)	Pre-programmed delivery of small quantities of insulin at a constant rate and can deliver intermittent bolus doses throughout the day as necessary
Self-monitoring of blood glucose (SMBG)	The patient takes a sample of blood through a finger prick and submits the sample to a glucose meter
Continuous glucose monitor (CGM)	A device that continuously monitors and records interstitial fluid glucose levels and has three components: (1) a disposable subcutaneous sensor, (2) transmitter, and (3) monitor (or receiver). Some CGM systems are designed for short-term diagnostic or professional use. Other CGM systems are designed for long-term client use.
Retrospective continuous glucose monitor (Retro-CGM)	Records glucose measurements for later review in a clinician's office to help with glycemic control planning. Glucose levels are continuously monitored via an inserted sensor in the abdomen
Real-time continuous glucose monitor (Rt-CGM)	Provides immediate glucose measurements on a display, most rt-CGM systems have alarms to warn of dangerous glucose levels
Sensor-augmented pump (SAP)	Combines CSII and rt-CGM technologies
Closed-loop system/artificial pancreas (AP)	The artificial pancreas, known as closed-loop control of blood glucose in diabetes, is a system combining a glucose sensor, a control algorithm, and an insulin infusion device.

Overview of New CGM Technology

Remote Mobile Communication Devices

Remote mobile communication devices allow clinicians and others to monitor blood glucose levels continuously via computers, smart phones and wrist-watches (e.g., Apple Watch). Three remote mobile communication devices were approved by the Food and Drug Association in 2015: Dexcom Share, Dexcom G5 with Bluetooth, and MiniMed Connect. Remote mobile communication devices link to CGM systems wirelessly or via a docking station. The remote

CGM device then uploads CGM data, sends it a cloud server, and then allows users to view their CGM data via a smart phone or wrist watch device app (Bailey et al., 2016; Dexcom, 2015).

An open source software called Nightscout has also been developed that allows individuals to view CGM data from any remote CGM device and a few newer generation CGM systems (Dexcome G4, Metronic 530g/Veo, Medtronic 640g, and FreeStyle Libre). Once downloaded to an electronic device, Nightscout then collects data from the CGM receiver, sends it to a cloud server, and is downloaded to a customized website. According to the Nightscout Project website, the software was developed and is maintained by volunteers, is not Health Insurance Portability and Accountability Act (HIPPA) privacy compliant, is highly experimental and considered to be an investigational and educational tool to learn about this technology, and should be used at an individual's own risk (Nightscout contributors, 2015; The Nightscout Project, 2016).

Previous Related MED Report Summaries

The Medicaid Evidence-based Decisions Project (MED) published nine reports on diabetes between 2009 and 2015 (four of which are now archived). Summaries of six of these topics (five non-archived, and one archived) can be found in the following document: Diabetes: Summary of MED Reports and Resources (2015). All of these reports are available on the MED Clearinghouse. One recent MED report addresses CGM. The conclusions of this report are highlighted below.

Continuous Glucose Monitoring for Children, Adolescents and Adults with Type I and Type II Diabetes (2013) (Little et al., 2013)

> This MED report found that use of real-time CGM in patients with type 1 diabetes may result in lower HbA1c levels compared to SMBG, although the decrease was small and potentially not clinically significant. The authors concluded that there was insufficient evidence to evaluate the use of real-time CGM in pediatric patients, pregnant patients, or adults with type II diabetes. This review also evaluated the effect of CGM with CSII in patients with type 1 diabetes and found that the combination may lead to statistically and clinical significant reductions in HbA1c. The review did not identify any information on subgroup populations, and reported mild adverse events including bleeding, pain, tenderness, sensitivity, itching, swelling, or bruising.

Methods

Center staff updated the search strategy conducted in the 2013 MED report *Continuous Glucose Monitoring for Children, Adolescents, and Adults with Type I and Type II diabetes* covers (Little et al., 2013). This consisted of searching MED core sources for studies on the effectiveness of CGM vs. SMBG for individuals with type 1 and type 2 diabetes. Searches were limited to the English language and systematic reviews, meta-analyses, and technology assessments published after January 2012. Search term included "diabetes and glucose monitor*" or

"continuous glucose." Center staff also updated the primary source for this report (Hayes, 2015) using MEDLINE (PubMed).

One Center staff independently evaluated the quality of the included systematic reviews and RCTs for this report and a second staff member checked the rating using a quality assessment process highlighted in Appendix A. It is important to note that Center staff only quality assessed the systematic review methods and did not assess the quality of the individual studies included in each review.

To identify coverage criteria for CGMs, staff searched federal and state payer policies using the following sources: the Medicare Coverage Database; Medicaid.gov; State Medicaid agency websites, provider manuals, and related state statute or administrative rule websites in the following states: Massachusetts, Minnesota, Oregon, Texas, and Washington. Staff also searched the following private payer policies: Aetna®, Anthem Blue Cross Blue Shield®, Cigna®, and UnitedHealthcare®. Search terms included "continuous glucose monitor", "glucose monitor", and "diabetes supplies" (Appendix A).

Findings

Search Results

Staff identified one fair-quality systematic review (Hayes, 2015) as a result of updating the 2013 MED report, which became the primary source for this report. After updating the search used in the Hayes (2015) review, staff identified one additional poor-quality RCT (Wei et al., 2016) focusing on the effectiveness of CGM for glycemic control in individuals with type 1 and type 2 diabetes. Staff also identified five state Medicaid and three private payer coverage policies. Continuous glucose monitors are considered precautionary under Medicare and therefore are not a covered DME benefit (Centers for Medicare and Medicaid Services, 2015).

Systematic Review

Hayes (2015) searched MEDLINE (PubMed) and Embase® databases from January 2000 to July 2015 for RCTs comparing the effectiveness of CGM as an adjunct to SMBG vs. SMBG alone for glycemic control among individuals with type 1 or type 2 diabetes. Hayes (2015) included studies of pediatric and adult patients as well as pregnant women with pregestational diabetes or who developed gestational diabetes. Studies that had less than 50 participants, less than 1-month of CMG follow-up, focused on CMG as a component of a closed-loop system, and only evaluated the GlucoWatch (a CMG technology that hasn't been commercially available since 2007) were excluded. Twenty-three RCTs and one randomized crossover trial met inclusion criteria (Hayes, 2015). Table 3 and Appendix B provide a description of study characteristics.

Hayes (2015) graded the quality of the body of evidence for each outcome, HbA1c, glycemic control, maternal weight gain, and birthweight, as moderate. Hayes used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group

approach for rating outcomes. All the included studies started out as good quality due to their study design (RCT), but were downgraded to moderate for the following reasons:

> Relatively small sample size, short treatment period, no blinding of assessment to treatment, brief or no follow-up after CGM ended, insufficient follow-up time, lack of data on long-term health outcomes, unusually high rate of patients dropping out of study or failing to follow study protocol, and combining data for pediatric and adult patients in the study population but not reporting outcomes separately for pediatric versus adult patients (p. 23).

Hayes (2015) also used its standard rating system (Table 2) for each population and indication (Table 2). The use of CGM in adults with type 1 diabetes who have not achieved adequate glycemic control, despite frequent SMBG, received a "B" rating indicating that there is some proven benefit of CGM in this population. The use of CGM in adults with type 2 diabetes and adolescents and children with type 1 diabetes received a "C" rating indicating that there is some potential but unproven benefit of CGM in these populations. The use of CGM in adolescents and children with type 2 diabetes and in pregnant women with pregestational (type 1 or 2 diabetes) or with gestational diabetes received a "D2" rating indicating that there is insufficient evidence to assess the safety or impact of CGM in these populations.

Table 2. Hayes' Rating for CGM per Population and Indication

Indication	Rating	Rating Justification
Adults with T1D who have not achieved adequate glycemic control despite frequent SMBG	B[1]	This Rating reflects highly consistent findings that CGM is beneficial in studies in which data for pediatric and adult patients with type 1 diabetes are combined, as well as some positive findings concerning the benefits of CGM in studies of only adult patients with type 1 diabetes (p. 68).
Adults T2D	C[2]	This Rating reflects some positive, but inconsistent, findings concerning the benefits of CGM in this diabetic population (p. 68).
Children and Adolescents T1DM who have not achieved adequate glycemic control despite frequent SMBG	C[2]	This Rating reflects highly consistent findings that CGM is beneficial in studies in which data for pediatric and adult patients with type 1 diabetes are combined, as well as somewhat consistent findings that CGM is not beneficial in studies of only pediatric patients with type 1 diabetes (p. 68).

[1]**Some proven benefit.** Published evidence indicates that safety and impact on health outcomes are at least comparable to standard treatment/testing. However, there are outstanding questions regarding long-term safety and impact on health outcomes, clinical indications, contraindications, optimal treatment/testing parameters, and/or effects in different patient subpopulations. Drugs, biologics, and devices with a B rating have FDA approval, but not necessarily for the specific clinical application(s) under consideration.

[2]**Potential but unproven benefit.** Some published evidence suggests that safety and impact on health outcomes are at least comparable to standard treatment/testing. However, substantial uncertainty remains about safety and/or impact on health outcomes because of poor-quality studies, sparse data, conflicting study results, and/or other concerns.

Children T2DM	D2[3]	This Rating reflects the paucity of evidence concerning use of CGM in this diabetic population (p. 68).
Pregnant women with pregestational type 1 or type 2 diabetes or with gestational diabetes.	D2[3]	This Rating reflects the small number of available studies that evaluate CGM in pregnant women (p. 68).

Individual Studies from Updated Hayes (2015) Review

Wei (2016) conducted an open-label RCT evaluating the effectiveness of retro-CGM vs. SMBG among women with gestational diabetes. The mothers were enrolled in the study at 24-weeks of gestation. Women in the retro-CGM group were asked to wear the device at 24 to 28 weeks gestation or 28 to 36 weeks gestation. All women in the study received dietary counselling.

Summary of Findings

The following findings section is stratified by age group and diabetes type (e.g., adults with type 1 diabetes). Some studies did not separate results by age group and those findings are presented in their own section (e.g., adults, children, and adolescents with type 1 diabetes).

Adults – Type-1 Diabetes

Change in HbA1c Levels

Hayes (2015) identified four studies evaluating the effect of CGM as a supplement to SMBG vs. SMBG alone among adults with type 1 diabetes (Battelino et al., 2012; Chico, Vidal-Rios, Subira, & Novials, 2003; Hirsch et al., 2008; Tamborlane et al., 2008). Two studies (Battelino et al., 2012; Tamborlane et al., 2008) found that constant use of Rt-CGM for 6-months, compared to SMBG alone, was associated with statistically significant mean reductions in HbA1c (-0.41% [95% CI -0.28% to -0.53%] and -0.53% [age ≥25; 95% CI -0.71% to -0.35%]). Only Tamborlane (2008) showed a clinically meaningful reduction in HbA1c in the CGM vs. SMBG groups. Two studies found that constant use of Rt-CGM for 3 months (Hirsch et al., 2008) and the intermittent use of Retro-CGM (1 3-day session over 3 months) (Chico et al., 2003) did not result in statistically significant differences in HbA1c between the CGM and SMBG groups.

Occurrence of Severe Hypoglycemic Events and Adverse Events

No studies on adults with type 1 diabetes reported severe hypoglycemic or other serious adverse events. Hirsch (2008) and Battelino (2012) did not report severe hypoglycemic or adverse events by age group, so their results are reported in the Adults, Children, and Adolescents – Type 1 Diabetes section of this report.

[3] **Insufficient evidence.** There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management.

Adults – Type-2 Diabetes

Change in HbA1c Levels

Five studies in the Hayes (2015) review focused on the effectiveness of CGM vs. SMBG alone among adults with type 2 diabetes (Allen, Fain, Braun, & Chipkin, 2008; Blackberry et al., 2014; Ehrhardt, Chellappa, Walker, Fonda, & Vigersky, 2011; Tildesley et al., 2013; Yoo et al., 2008). Three of these studies showed statistically and clinically meaningful reductions in HbA1c (Allen et al., 2008; Ehrhardt et al., 2011; Yoo et al., 2008). Ehrhardt (2011) found that constant use of Rt-CGM for 52-weeks led to a -0.60% mean reduction in HbA1c in comparison to the SMBG group (p=0.002). Another study (Yoo et al., 2008) found that intermittent use of Rt-CGM (three 3-day sessions over 3 months) resulted in statistically significant reductions in mean HbA1c in comparison to using SMBG alone (mean difference -0.70%; p=0.004).

Allen (2008) evaluated the intermittent use of Retro-CGM (two 3-day sessions over 2-months) with a physical activity counselling program and diabetes education (including SMBG) vs. diabetes education (including SMBG) alone. It is important to note that the primary focus of the intervention in Allen (2008) was the effect of combining CGM with a 5-step physical activity counselling methodology (reviewing CGM graphs, outline benefits of physical activity, assess confidence in changing physical activity, prescribe physical activity program, and discuss normal response to starting a physical activity program). Allen (2008) found a statistically significant reduction in HbA1c from baseline in the CGM + physical activity counselling + diabetes education (including SMBG) vs. diabetes education (including SMBG) alone group (mean difference -0.84%, p<0.05). Allen (2008) did not adjust for baseline HbA1c, so these results may be biased. Blackberry (2014) and Tildesley (2014) did not report statistically significant changes in HbA1c between intermittent use Retro-CMG (three 3-day sessions over 24-weeks) or constant use Rt-CGM for 6-months vs. SMBG groups.

Occurrence of Severe Hypoglycemic Events and Adverse Events

Two studies (Blackberry et al., 2014; Tildesley et al., 2013) did not find statistically significant differences in hypoglycemic events between intermittent use Retro-CMG (three 3-day sessions over 24-weeks) or constant use Rt-CGM for 6-months and SMBG groups (2 vs. 0 events, p=0.17; number of events not reported). The other studies either reported no clinically symptomatic hypoglycemic events (Yoo et al., 2008) or did not mention severe hypoglycemic events in their results (Allen et al., 2008; Ehrhardt et al., 2011). One study (Tildesley et al., 2013) reported two minor adverse events among Rt-CGM participants (infection and cyst development around sensor). All other studies did not report adverse events.

Adults – Mixed Population Type 1 and Type 2 Diabetes

Change in HbA1c Levels

Three studies included adults with both type 1 and type 2 diabetes and did not stratify results (Cooke et al., 2009; New, Ajjan, Pfeiffer, & Freckmann, 2015; Tanenberg et al., 2004). Cooke

(2009) included adults with type 1 (40%) and type 2 (60%) diabetes and compared intermittent CGM (six 3-day sessions over 18-months) and SMBG. Tanenberg (2004) included adults with type 1 (89%) and type 2 (9%) and compared intermittent use of CGM (2 3-day sessions over 3 months) and SMBG groups. New (2015) included adults with type 1 (86.9%) and type 2 (13.1%) diabetes and compared constant use of Rt-CGM with no alarm, constant use of Rt-CGM with alarm, and SMBG groups for 100-days. None of these studies found statistically significant differences in HbA1c between CGM vs. SMBG groups.

Occurrence of Severe Hypoglycemic Events and Adverse Events

Tanenberg (2004) reported no statistical difference in the number of severe hypoglycemic events in the intermittent use of CGM (2 3-day sessions over 3 months) vs. SMBG group (2 vs. 1 event). No other studies that combined type 1 and type 2 diabetes adult populations were identified that analyzed severe hypoglycemic events. Cook and colleagues (2009) observed twenty-eight adverse events related to skin irritation among the Retro-CGM (GlucoWatch) group. Two participants in the Retro-CGM (MiniMed) panicked while wearing the device and had it removed in the emergency department. New (2015) reported 13 non-serious adverse events associated with using glucose sensors (bleeding, erythema, and itching).

Children and Adolescents – Type-1 Diabetes

Change in HbA1c Levels

Six studies in Hayes (2015) evaluated the effectiveness of CGM as a supplement to SMGB vs. SMBG alone among children with type 1 diabetes. Five of these studies (Bukara-Radujkovic, Zdravkovic, & Lakic, 2011; Hirsch et al., 2008; Kordonouri et al., 2010; Mauras et al., 2012; Tamborlane et al., 2008) found no statistically significant differences in mean HbA1c among participants using CMG constantly (or near constantly) for 6 to 12-months vs. SMBG. One study (Battelino et al., 2012) found that participants who had the sensor activated in their Rt-CGM device and used it constantly for 6-months observed a statistically significant mean reduction in HbA1c in comparison to the SMBG group (-0.46%, 95% CI -0.26% to -0.66%).

Occurrence of Severe Hypoglycemic Events and Adverse Events

One study (Kordonouri et al., 2010) reported statistically significantly fewer severe hypoglycemic events in the constant use of Rt-CGM for 12-months vs. SMBG group (0/76 vs. 4/78 events per group, p=0.046). Three studies reported no differences in hypoglycemic events (Bukara-Radujkovic et al., 2011) or severe hypoglycemic events (Mauras et al., 2012; Tamborlane et al., 2008) among the constant use of Rt-CGM for 6-months vs. SMBG group. Three studies reported adverse events occurring among study participants. Hirsch (2008) reported that one patient experienced two skin abscesses at the insulin infusion site and one experienced diabetic ketoacidosis in the Rt-CGM group. Tamborlane (2008) reported that two participants experienced cellulitis related to sensor use in the Rt-CGM group and one participant reported dizziness during a blood draw in the control group. Battelino (2012) reported that 178 non-serious adverse events occurred among study participants (80 in Rt-CGM

sensor on and 98 in the Rt-CGM sensor off group). All other studies did not report adverse events.

Children and Adolescents – Type-2 Diabetes

No studies on the effectiveness of CGM vs. SMBG among children and adolescents with type 2 diabetes were found.

Adults, Children, and Adolescents – Type-1 Diabetes

Change in HbA1c Levels

Hayes identified seven studies that evaluated the effectiveness of CGM + SMBG vs. SMBG alone in combined adult and pediatric populations with type 1 diabetes. Six studies (Battelino et al., 2011; Beck et al., 2009; Deiss et al., 2006; O'Connell et al., 2009; Raccah et al., 2009; Riveline et al., 2012) found that nearly constant to constant use of Rt-CGM for 3 to 12 months resulted in statically significant reductions in HbA1c in comparison to SMBG alone groups. Only one of these studies showed clinically meaningful reductions in HbA1c in the CGM vs. SMBG group (Deiss et al., 2006). One study (Tamborlane et al., 2008) found that found no statistically significant differences in mean HbA1c among participants aged 15 to 24 years old using Rt-CMG constantly (or near constantly) for vs. SMBG at 26-weeks follow-up.

Deiss (2009) reported a statistically significant mean reduction among individuals using Rt-CGM constantly compared to the SMBG group at 3-months (mean difference -0.60%, P=0.008). Raccah (2009) found that participants who were fully compliant with the protocol (wore the Rt-CGM device at least 70% of the time) saw a greater reduction in HbA1c than the SMBG group at 3-months follow-up (mean difference -0.41%, P=0.004). Raccah (2009) did not adjust for baseline HbA1c, so these results may be biased. Riveline (2012) found that at 12-months follow-up, the Rt-CGM group experienced greater reductions in HbA1c than the SMBG group (mean difference -0.46%, P<0.0001). Battelino (2011) reported a statistically significant reduction in mean HbA1c in the Rt-CGM vs. SMBG group (-0.27%, 95% CI -0.47 to -0.07) at 6-months. Beck (2009) observed a treatment group reduction of -0.34% between the Rt-CGM and SMBG groups at 26 weeks (95% CI -0.49 to -0.20). From baseline to 3-months follow-up, O'Connell (2009) reported a -0.43% reduction in HbA1c between the Rt-CGM vs. SMBG group at 3-months (95% CI -0.19 to -0.75).

Occurrence of Severe Hypoglycemic Events and Adverse Events

Most studies with mixed age populations with type 1 diabetes reported few severe hypoglycemic events in the Rt-CGM and SMBG groups. Only one study (Hirsch et al., 2008) reported statistically significantly fewer severe hypoglycemic in the constant use of Rt-CGM vs. SMBG group at 3-months follow-up (3/72 vs. 11/66 events per group, p=0.04). Beck (2009) reported non-statistically significant differences in proportion of Rt-CGM and SMBG participants who experienced one or more severe hypoglycemic events in the past 6 months (10% vs. 11%, P=1.0). Deiss (2006) reported two severe hypoglycemic events in the Rt- CGM group and none in the SMBG group. Similarly, Raccah (2009) reported one severe hypoglycemic

event in the RT-CGM group and none in the SMBG group. Battelino (2012) reported non-significant differences in diabetic ketoacidosis events in the Rt-CGM vs. SMBG group (2 vs. 4 events, p=0.47).

In comparison, Riveline (2012) reported 20 incidences of severe hypoglycemia in the Rt-CMG groups at 12-months follow-up (15 in the patient-led group and 5 in the physician-led group); seven of these events in the patient-led CGM group were attributable to one participant. There were also five severe hypoglycemic events in the SMBG group; however, the difference between Rt-CGM and SMBG groups were non-significant at 12-months follow-up (test statistics were not reported).

Battelino (2011) reported four serious adverse events unrelated to the device at 6-months follow-up. O'Connell (2009) reported that one participant in the Rt-CGM group was admitted to the hospital for treatment of new-onset depression. Raccah (2009) reported nine serious adverse events at 6-months follow-up. Two episodes of ketoacidosis occurred in the Rt-CGM group. Three episodes of ketoacidosis and four other serious adverse events not related to the device (details on these events were not included in the study) were reported in the SMBG group. Riveline (2012) reported two episodes of diabetic ketoacidosis in the Rt-CGM groups at 12-months follow-up. Tamborlane (2008) reported two participants experiencing diabetic ketoacidosis and kidney laceration in the SMBG group and two participants experiencing anxiety and depression and seizure not caused by hypoglycemia in the Rt-CGM group at 26-weeks.

Pregnant Adults

Change in HbA1c Levels

Three from Hayes (2015) (Kestila, Ekblad, & Ronnemaa, 2007; Murphy et al., 2008; Secher, Ringholm, Andersen, Damm, & Mathiesen, 2013) and one from the updated PubMed search (Wei et al., 2016) evaluated the effect of Retro-CGM vs. SMBG alone among pregnant women with pregestational and gestational diabetes. Murphy (2008) found that among women with pregestational diabetes , intermittent use of Retro-CGM from 8-weeks to 32-weeks of gestation (up to 7 days at 4 to 6 week intervals) resulted in a statistically and clinically significant reduction in HbA1c (-0.60%, P=0.007) in comparison to SMBG alone. Secher (2013) found no significant difference in HbA1c levels among women with pregestational diabetes (type 1 and type 2) between intermittent use of Retro-CGM (five 3-day sessions over 25-weeks) and SMBG groups at 33 weeks (mean difference in HbA1c between groups not reported). Wei (2016) Kestila (2007), who included women with gestational diabetes in their study, did not report on HbA1c as an outcome. Wei (2016) found no statistically significant differences in HbA1c levels among women with gestational diabetes who used Retro-CGM during 24 to 28 weeks of gestation (group 1) and 28 to 36 weeks of gestation (group 2) vs. SMBG.

Pregnancy- and Birth-related Outcomes

Secher (2013) found no statistically significant differences in primary and secondary pregnancy and perinatal outcomes (small-for-gestational age, preterm delivery, and/or neonatal hypoglycemia) or other pregnancy and perinatal outcomes between intermittent use of Retro-CGM (five 3-day sessions over 25-weeks) and SMBG groups. Murphy (2008) found that infants born to women in the Retro-CGM group had marginally significant reductions in mean birth weight in comparison to the SMBG group (mean standard deviation score 0.9 vs. 1.6, difference 0.7, 95% CI 0.0 to 1.3). Murphy (2008) also observed a 64% reduction in the odds of fetal macrosomia (birth weight above 8 lbs. 13 ounces regardless of gestational age) among women in the Retro-CGM vs. SMBG group (OR 0.36, 95% CI 0.13 to 0.98). Kestila (2007) found no statistically significant differences between the intermittent use of Retro-CGM (4 times per day, follow-up time not reported) and SMBG groups based on rates of caesarian section or preeclampsia, gestational age at delivery, birth weight, or neonatal hypoglycemia. Wei (2016) did not observe statistically significant differences in maternal or neonatal outcomes among pregnant women with gestational diabetes who used Retro-CGM during 24 to 28 weeks of gestation (group 1) and 28 to 36 weeks of gestation (group 2) vs. SMBG.

Occurrence of Severe Hypoglycemic Events and Adverse Events

Center staff only identified one study that reported on the occurrence of severe hypoglycemic events among pregnant women (Secher et al., 2013). During the 33-week study period, Secher (2013) observed 59 episodes of severe hypoglycemia among 19 women with pregestational type 1 diabetes and 15 episodes of severe hypoglycemia among five women with pregestational type 2 diabetes. However, there were no significant differences in number of severe hypoglycemic events between the Retro-CGM and SMBG groups among women with type 1 diabetes (11% vs. 19%, P=0.28).

Table 3. Study Characteristics and Primary Results of Individual Studies within Hayes (2015) and Updated PubMed Search

Study (Year)	N	Follow-up	Baseline HbA1c	Primary Results	
				Change HbA1c from baseline to end of study	**95% CI and/or p-value for test comparing between group differences**
Individual Studies from Hayes (2015)					
Adults T1DM					
Battelino (2012)	81 (81)	6 months	CGM on: 8.40% CGM off: 8.10%	**Mean diff:-0.41%**	(-0.28% to -0.53%) P<0.001
Chico (2003)	75 (75)	3 months	T1D CGM: 8.30% T1D SMBG: 8.00% T2D CGM: 7.40%	CGM: 8.30% to 7.50% SMBG: 8.00% to 7.50% **Mean diff: -0.30%**[1]	Test for differences between groups not reported
Hirsch (2008)	49 (49)	6 months	CGM: 8.37% SMBG: 8.30%	CGM: 8.37% to 7.68% SMBG: 8.30% to 7.66% **Mean diff: -0.10%**	p=0.80
Tamborlane (2008)	98 (98)	6 months	CGM: 7.60% SMBG: 7.60%	CGM: -0.50% SMBG: 0.02% **Mean diff: -0.53%**	(-0.71% to -0.35%) p<0.001
Adults T2D					
Allen (2008)	52 (46)	8 weeks	CGM + PA counsel: 8.40% SMBG: 8.30%	CGM: -1.16% SMBG group:-0.32% **Mean diff:-0.84%**[1]	P<0.05; exact p-value not reported
Blackberry (2014)	92 (89)	24 weeks	All: 9.90%	CMG: -2.70% SMBG: -2.40% **Mean diff: -0.30%**	p=0.31
Ehrhardt (2011)	100 (100)	12 months	CMG: 8.40% SMBG: 8.20%	CGM: -1.0% SMBG:-0.50% **Mean diff: -0.60%**	p=0.002
Tildesley (2013)	50 (50)	6 months	CGM: 8.80%	CGM: 8.80% to 7.49%	p=0.081

Study (Year)	N	Follow-up	Baseline HbA1c	Primary Results	
			SMBG: 8.79%	SMBG: 8.79% to 7.96% **Mean diff: -0.48%**[1]	
Yoo (2008)	57 (57)	3 months	CGM: 9.10% SMBG: 8.70%	CGM: 9.10% to 8.00% SMBG: 8.70% to 8.30% **Mean diff: -0.70%**	p=0.004
Adults T1D &T2D					
Cooke (2009)	404 (330)	18 months	CGM: 9.00% SMBG: 9.40%	CGM: -0.50% SMBG: -0.50% **Mean diff: 0%**	Authors report no statistically significant difference, p-value not reported
New (2015)	145 (128)	100 days	CGM no alarm: 8.10% CGM alarm: 8.20% SMBG: 8.0%	CGM no alarm: 8.10% to 8.0% CGM alarm: 8.20% to 8.10% SMBG: 8.00% to 8.00% **Mean diff: -0.10%**	Authors report no statistically significant difference, p-value not reported
Tanenberg (2004)	109 (109)	12 weeks	CGM: 9.10% SMBG: 9.00%	CGM: 8.30% SMBG: 8.30% **Mean diff: -0.10%**	p=0.70
Children and Adolescents T1D					
Battelino (2012)	72 (72)	6 months	CGM on: 8.50% CGM off: 8.60%	**Mean diff: -0.46%**	(-0.32% to -0.55%) P<0.001
Bukara (2011)	80 (80)	6 months	CGM: 10.00% SMBG: 10.20%	CGM: 10.00% to 8.60% SMBG: 10.20% to 8.90% **Mean diff: -0.10%**[1]	p=0.71
Hirsch (2008)	40 (40)	6 months	CGM: 8.82% SMBG: 8.59%	CGM: 8.82% to 8.02% SMBG: 8.59% to 8.21% **Mean diff: -0.42%**	p=0.10
Kordonouri (2010)	160 (154)	12 months	CGM: 11.20%	CGM: 7.40%	p=0.45

Study (Year)	N	Follow-up	Baseline HbA1c	Primary Results	
			SMBG: 11.50%	SMBG: 7.60% **Mean diff: 0.10%**[1]	
Mauras (2012)	146 (137)	26 weeks	CGM: 7.90% SMBG: 7.90%	CGM: 7.80% SMBG: 7.80% **Mean diff: 0%**	p=0.79
Tamborlane (2008)	114 (114)	26 weeks	CGM: 8.00% SMBG:7.90%	CGM: -0.37% SMBG: -0.22% **Mean diff: -0.15%**	p=0.29
Adults, Children and Adolescents T1DM					
Battelino (2011)	120 (116)	6 months	CGM: 6.92% SMBG: 6.91%	**Mean diff: -0.27%**	(-0.47% to -0.7%) p=0.008
Beck (2009)	129 (126)	26 weeks	CGM: 6.40% SMBG: 6.50%	CGM:0.020% SMBG: 0.33% **Mean diff: -0.34%**	(-0.49% to -0.20) p<0.001
Deiss (2006)	156 (156)	3 months	Cont. CGM: 9.50% Interm. CGM: 9.60% SMBG: 9.70%	Const. CGM vs. SMBG: -1.00% vs. -0.40% **Mean diff: -0.60%** Interm. CGM vs. SMBG at 3-months not reported	P=0.008
O'Connell (2009)	62 (55)	3 months	CGM: 7.30% SMBG: 7.50%	CGM: 7.10% SMBG: 7.80% **Mean diff: -0.43%**	(-0.19% to -0.75%) p=0.009
Raccah (2009)	115 (100)	6 month	CGM: 9.11% SMBG: 9.28%	CGM: -0.96% SMBG: -0.55% **Mean diff: -0.41%**[1]	P=0.004
Riveline (2012)	197 (178)	12 months	CGM patient-led: 9.00% CGM provider-led: 8.90%	CGM patient + provider-led: -0.48%	p<0.0001

Study (Year)	N	Follow-up	Baseline HbA1c	Primary Results	
			SMBG: 8.80%	SMBG: -0.02% **Mean diff: -0.46%**	
Tamborlane (2008)	110 (110)	26 weeks	Age 15-24 years CGM: 8.00% SMBG:7.90%	CGM: -0.18% SMBG: -0.21% **Mean diff: 0.03%**	p=0.52
Pregnant Adults (Gestational Diabetes)					
Kestilä (2007)	73 (73)	Not reported	CGM: 5.40% SMBG: 5.30%	Did not report on HbA1c	
Pregnant Adults (Pre-Gestational T1D & T2D)					
Murphy (2008)	71 (71)	28 weeks	CGM: 7.20% SMBG: 7.40%	CGM: 5.80% SMBG: 6.40% **Mean diff: -0.60%**	p=0.007
Secher (2013)	154 (149)	33 weeks	CGM: 6.60% SMBG: 6.80%	CGM: 6.00% SMBG: 6.10% **Mean diff: 0.10%**[1]	p=0.63
Updated PubMed Search					
Pregnant Adults (Gestational Diabetes)					
Wei (2016)	106 (106)	36 weeks	CGM:5.70% SMBG: 5.80%	CGM: 5.50% SMBG: 5.60% **Mean diff: 0%**[1]	P=0.09

Abbreviations: Const. CGM – Constant Continuous Glucose Monitoring; Interm. CGM – Intermittent Continuous Glucose Monitoring; Mean diff – Mean difference; PA counsel – Physical Activity counselling; Rt-CGM – Real-time Continuous Glucose Monitor; Retro-CGM – Retrospective Continuous Glucose Monitor; SMBG – Self-Monitoring Blood Glucose; T1D – Type 1 Diabetes; T2D – Type 2 Diabetes

1 Results may be biased because study did not adjust for baseline HbA1c

Coverage Policies for Continuous Glucose Monitors

The state Medicaid and private payer policies are summarized below. Appendices C and D detail the full coverage policies. Staff searched federal, state (Massachusetts, Minnesota, Oregon, Texas, and Washington), and private payer (Aetna®, Anthem Blue Cross Blue Shield®, Cigna®, and UnitedHealthcare®) policies

Medicaid Coverage Policies for Continuous Glucose Monitors

Medical necessity criteria

- Type 1 diabetes only (Massachusetts, Minnesota, Oregon)
- Type 1 diabetes and pregnant women with diabetes (Texas)
- All insulin dependent diabetes (Washington)

History of hypoglycemia

- History of recurrent hypoglycemia (Oregon)
- History of severe hypoglycemia less than 50 mg/dL with unawareness due to age or cognitive function (Minnesota)
- Needs to be unexplained large fluctuations in daily, preprandial blood glucose and episodes of ketoacidosis or hospitalization for uncontrolled glucose (Texas)
- One or more severe episodes of hypoglycemia or be enrolled in an Institutional Review Board-approved trial (Washington)

Other medical necessity criteria

- Age 18 and younger (Washington)
- HbA1c levels > 8% despite compliance with therapy (Oregon)

Prior Authorization

- All reviewed state Medicaid policies require prior authorization (PA)
- No PA if required for the disposable sensors (HCPCS code A9276) (Minnesota)

Documentation

- Frequent self-monitoring and appropriate modifications to insulin regimen (Minnesota)
- Medical necessity criteria (Texas)

Not covered

- Closed loop systems (Washington)

Private Payer Coverage Policies

Medical necessity criteria – Coverage criteria for long-term use of CGM (more than 72 hours)

- Adults 25 years and older with type 1 (Aetna and Cigna)
- Individuals less than 25 years with type 1 who have had:
    - Recurrent episodes of severe hypoglycemia (defined as hypoglycemia [blood glucose less than 50 mg/dL]) (Aetna and Cigna)
    - Unawareness that required assistance from another person to administer oral carbohydrate, glucagon, or other resuscitative actions (Cigna)
    - Appropriate modifications in insulin regimen and compliance with frequent self-monitoring (at least 4 fingersticks/day) (Aetna and Cigna)
- Type 1, no age restriction in criteria (UnitedHealthcare)
- Long-term use in a type 2 diabetic with recurrent, severe hypoglycemic events despite appropriate modifications in insulin therapy, and compliance with frequent SMBG (Cigna only)
- Hypoglycemia unawareness and/or frequent episodes of hypoglycemia (UnitedHealthcare)

Additional medical necessity criteria from Cigna includes (any of the following):

- History of diabetic ketoacidosis
- Positive autoantibody test showing islet cell cytoplasmic autoantibodies or glutamic acid decarboxylase autoantibodies
- Fasting C-peptide level ≤ 110% of the lower limit of normal of the laboratory's measurement method AND a concurrently obtained fasting glucose ≤ 225 mg/dL
- Renal insufficiency with a creatinine clearance ≤ 50 ml/minute AND a fasting C-peptide level ≤ 200% of the lower limit of normal of the laboratory's measurement method

Not covered

Atena

- Biostar® artificial pancreas
- Artificial pancreas device system (CGM + insulin pump with a low glucose suspend feature) an equally acceptable alternative to a standard insulin pump and CGM for medically necessary indications
- GlucoWatch® biographer monitor

Cigna

- Additional software or hardware required for downloading data to a device

- Combination devices that include a home blood glucose monitor combined with a cellular telephone or other device not specifically indicated for the management of diabetes mellitus
- Remote glucose monitoring device (e.g., mySentry)

UnitedHealthcare

- Remote glucose monitoring device

Summary and Limitations

This report sought to address the question of whether CGM in comparison to SMBG results in improved blood glucose levels (i.e., HbA1c), fewer severe hypoglycemic events, and improved clinical outcomes among individuals with type 1 diabetes, insulin-requiring type 2 diabetes, or pregnant women with gestational diabetes. Center staff identified one fair-quality systematic review and one low-quality RCT. Five studies (out of 24) comparing CGM vs. SMBG found statistically and clinically meaningful reductions in HbA1c ranging from (-0.53% to -0.7%). These results were found in the following populations: adult type 1 diabetes (one study), mixed age type 1 diabetes populations (one study), adult type 2 diabetes (two studies), and pregnant adult populations (one study) in comparison to SMBG. One study comparing CGM + physical activity counselling + diabetes education (including SMBG) compared to diabetes education (including SMBG) alone among adults with type 2 diabetes found statistically and clinically meaningful reductions in HbA1c (-0.84%). However, this result may be biased because the study did not take into account baseline HbA1c in their data analysis. Two studies (one in pediatric patients with type 1 diabetes and one in the mixed age type 1 diabetes population) demonstrated that CGM compared to SMBG statistically significantly reduced severe hypoglycemic events. Studies of type 1 diabetes children or combined type 1 diabetes adult and pediatric populations reported few serious adverse events associated with the CGM device.

There are some limitations of the Hayes (2015) report and the individual studies identified in that report and by our updated search strategy that should be considered when interpreting the key findings. First, there was a lack of transparency around how studies were selected for inclusion or exclusion in the primary evidence source. Hayes (2015) did not include an a priori design or protocol, a description of study selection (e.g., PRISMA diagram), or discuss the likelihood of publication bias. These omissions make it difficult to assess whether Hayes' literature search was sufficiently rigorous to identify all relevant studies. Hayes also does not give information on the quality assessment instrument or processes (i.e., independent review) they used to quality rate individual studies in their review. Most studies included in their review were downgraded from good to fair quality due to reasons already mentioned in the search results section of this report (p. 7). A glaring omission from this list is the potential for bias due to conflicts of interest. More than half of included studies were funded by the CGM device manufacturer (13 out of 24) or did not report this information (2 out of 24).

Another important limitation of the Hayes review was that they did not consider whether HbA1c reductions were clinically meaningful in their interpretation of results or in the final Hayes' Rating. Hayes' "B" rating for adults with type 1 diabetes who have not achieved adequate glycemic control despite frequent use of SMBG was based partially off of the "highly consistent findings that CGM is beneficial" in combined adult and pediatric populations. Even if we expand the clinically meaningful definition to include HbA1c reductions of at least -0.4%, only 4 out of 7 type 1 diabetes studies combining adult and pediatric populations would be considered clinically meaningful. Hayes' B rating for type 1 diabetes adults was also based off of "some positive findings" showing benefit in the type 1 diabetes adult only studies. One out of four studies reached both statistical and clinical significance at HbA1c ≥ -0.5%. If we expand the meaning of clinical significance to HbA1c ≥ -0.4%, only two out of four show a benefit of CGM vs. SMBG.

There are important gaps in the literature which limits our ability to determine the effectiveness of CGM vs. SMBG in all diabetes populations and on longer-term outcomes. There were few studies on pregnant adults and no studies on children with type 2 diabetes. Similarly, none of the included studies reported on longer-term outcomes, such as micro- or macrovascular disease or mortality. Although most studies did report on severe hypoglycemic events, most were underpowered to detect a differences between CGM and SMBG groups (rare events).

Finally, there were a large number of studies within the Hayes review that combined pediatric and adult populations, but did not stratify results by age. It is not clear why studies with combined pediatric and adult type 1 diabetes populations showed CGM had a positive benefit (although small and primarily not clinically meaningful) and pediatric and adult only studies showed CGM had little or no significant benefit, or had mixed results. Adolescents and young adults are also less likely to adhere to intensive insulin therapy and be less compliant with glucose monitoring over time (Tamborlane et al., 2008).

Only one of four trials demonstrated that CGM compared to SMBG was effective for glycemic control among pregnant women (gestational or pregestational diabetes). No studies were identified that analyzed the effectiveness of CGM in children with type 2 diabetes or long term outcomes. Overall, the conclusions of this report did not significantly differ from the 2013 MED report on CGM.

Appendix A: *Methods*

Center for Evidence-based Policy (Center) staff searched core Medicaid Evidence-based Decisions Project (MED) primary evidence sources. Searches were limited to references published in English. Staff limited searches to the last ten years. Core MED evidence sources include:

- Cochrane Library (Wiley Interscience)
- PubMed Health
- *BMJ Clinical Evidence*
- Agency for Healthcare Research and Quality (AHRQ)
- National Institute for Health and Care Excellence (NICE) – Evidence search
- Hayes, Inc.
- Blue Cross/Blue Shield Health Technology Assessment (HTA) program
- Veterans Administration Technology Assessment Program (VATAP)
- Washington State Health Technology Assessment Program
- MED Clearinghouse

PubMed Search

Database: PubMed
Search dates: April 2015 – March 7, 2016

(MiniMed OR (glucose AND blood AND (monitor OR sensor OR detection) AND (continuous OR subcutaneous OR dermal))) AND (random OR randomized OR randomised)*

Inclusion Criteria

Populations: Individuals with type 1, insulin-requiring type 2 diabetes mellitus or pregnant women with gestational diabetes

Interventions: Continuous glucose monitoring (retrospective or real-time)

Comparators: Self-monitoring of blood glucose (SMBG)

Outcomes: HbA1c, severe hypoglycemic events, morbidity, mortality, adverse events

Exclusion Criteria

Studies were excluded if they were not published in English or did not analyze outcomes of interest.

Quality Assessment

Methodological Quality of Included Studies

One Center staff member independently evaluated the quality of the included systematic reviews and RCTs for this report and a second staff member checked the rating using standard instruments developed and adapted by the MED Project that are modifications of the systems

in use by NICE and SIGN (Guyatt et al., 2008; National Institute for Health and Care Excellence (NICE), 2009; Scottish Intercollegiate Guidelines Network (SIGN), 2009).

In brief, good-quality systematic reviews include a clearly-focused question, a literature search sufficiently rigorous to identify all relevant studies, criteria used to select studies for inclusion (e.g., randomized controlled trials) and assess study quality, and assessment of similarities between studies to determine if combining them is appropriate for evidence synthesis. Fair-quality systematic reviews have incomplete information about methods that might mask important limitations or a meaningful conflict of interest. Poor-quality systematic reviews have clear flaws that could introduce significant bias.

Good-quality randomized controlled trials include a clear description of the population, setting, intervention, and comparison groups; a random and concealed allocation of patients to study groups; low dropout rates; and intention-to-treat analyses. Good-quality randomized controlled trials also have low potential for bias from conflicts of interest and funding source(s). Fair-quality randomized controlled trials have incomplete information about methods that might mask important limitations or a meaningful conflict of interest. Poor-quality randomized controlled trials have clear flaws that could introduce significant bias.

Appendix B: *CGM Device and Usual Care Description in Individual Studies*

Study (Year)	Insulin Delivery Method	CGM Device Type (All use SMBG in addition to CGM)	Usual Care
Adults T1D			
Battelino (2012)	CSII only	Rt-CGM (Paradigm) sensor on	Rt-CGM (Paradigm) sensor off, SMBG
Chico (2003)	T1DM, all MDI, some switched to CSII T2DM, MDI, CSII and oral drugs	Retro-CGM (MiniMed)	SMBG
Hirsch (2008)	CSII only (SAP vs. pump only)	Rt-CGM (Paradigm)	SMBG
Tamborlane (2008)	MDI and CSII in both groups	Rt-CGM (DevCom), SAP (Paradigm) OR Rt-CGM (Freestyle)	SMBG
Adult T2D			
Allen (2008)	N/A[1]	Retro-CGM (MiniMed)[2] + diabetes education + physical activity efficacy counselling[3]	SMBG + diabetes education
Blackberry (2014)	MDI and CSII in both groups	Retro-CGM (iPro)	SMBG
Ehrhardt (2011)	N/A[1]	Rt-CGM (DexCom)	SMBG
Tildesley (2013)	MDI only	Rt-CGM (Guardian)	Internet blood glucose monitoring system + SMBG
Yoo (2008)	Does not say[4]	Rt-CGM (Guardian)	SMBG
Adults T1D & T2D			
Cooke (2009)	MDI and CSII in both groups	Retro-CGM (GlucoWatch) OR Retro-CGM (MiniMed)	SMBG
New (2015)	MDI and CSII in both groups	Rt-CGM (Freestyle Navigator) + alarm OR Rt-CGM (Freestyle Navigator)	SMBG
Tanenberg (2004)	MDI and CSII in both groups	Retro-CGM (MiniMed)	SMBG
Children & Adolescents T1D			
Battelino (2012)	CSII only	Rt-CGM (Paradigm) sensor on	Rt-CGM (Paradigm) sensor off, SMBG

Bukara (2011)	MDI	Retro-CGM (MiniMed)	SMBG
Kordonouri (2010)	CSII only (SAP vs. pump alone)	Rt-CGM (Paradigm)	SMBG
Mauras (2012)	MDI and CSII in both groups	Rt-CGM (Freestyle Navigator) OR Rt-CGM (Paradigm)	SMBG
Tamborlane (2008)	MDI and CSII in both groups	Rt-CGM (DevCom), SAP (Paradigm) OR Rt-CGM (Freestyle)	SMBG
Adults, adolescents, & children T1D			
Battelino (2011)	MDI and CSII in both groups	Rt-CGM (FreeStyle Navigator)	SMBG
Beck (2009)	MDI and CSII in both groups	Rt-CGM (DexCom) OR SAP (Paradigm) OR Rt-CGM (Freestyle)	SMBG
Deiss (2006)	MDI and CSII in both groups	Rt-CGM (Guardian) continuous OR intermittent	SMBG
O'Connell (2009)	CSII only (SAP vs. pump alone)	Rt-CGM (Paradigm)	SMBG
Raccah (2009)	Transition from MDI to CSII (SAP or pump alone) during study	Rt-CGM (Paradigm)	SMBG
Riveline (2012)	Transition from MDI to CSII during study	Rt-CGM (FreeStyle Navigator, patient-led) OR Rt-CGM (FreeStyle Navigator, physician-led)	SMBG
Tamborlane (2008)	MDI and CSII in both groups	Rt-CGM (DevCom), SAP (Paradigm) OR Rt-CGM (Freestyle)	SMBG
Pregnant adults			
Kestilä (2007)	N/A; insulin was introduced during the study	Retro-CGM (MiniMed)	SMBG
Murphy (2008)	MDI and CSII in both groups	Retro-CGM (MiniMed)	SMBG
Secher (2013)	MDI and CSII in both groups	Retro-CGM (MiniMed)	SMBG
Individual Studies Updated PubMed Search – Pregnant adult			
Wei (2016)	Does not specify	Retro-CGM (MiniMed System Gold)	SMBG

Abbreviations: CSII – Continuous Subcutaneous Insulin Infusion; MDI – Multiple Daily Injections; N/A – Non-applicable; Rt-CGM – Real-time Continuous Glucose Monitor; Retro-CGM – Retrospective Continuous Glucose Monitor; SAP – Sensor Augmented Pump; SMBG – Self-Monitoring Blood Glucose; T1D – Type-1 Diabetes; T2D – Type-2 Diabetes

1 Participants are not taking insulin

2 Article does not say which CGM technology was used. Minimed Medtronic provided a small equipment grant, so made the assumption that this was the technology used in the study.

3 Physical activity counselling includes: (1) review CGMS graphs with each participant, (2) outline benefits of physical activity, (3) assess confidence in changing physical activity, (4) prescribe physical activity program, and (5) discuss normal responses to starting a physical activity program.

4 some are using insulin only and some are using insulin + oral hypoglycemic agent

Appendix C: *CGM Device Comparison Table*

Device Name	Diabetes Management Technology Type	Technology Description	Population Device Approved for	Device Approval Date
FreeStyle Navigator Continuous Glucose Monitoring System	Rt-CGM	Glucose sensor that reports glucose values continuously for up to 120 hours. These readings are used with fingerstick results to detect trends and patterns in glucose levels. After a 10 hour start-up period, the FreeStyle Navigator Continuous Glucose Monitoring System is calibrated with a fingerstick measurement taken by a built-in glucose meter. The device includes A sensor, sensor delivery unit, transmitter and receiver.	Individuals aged 18 and over, with diabetes	3/12/2008 (P050020)
MiniMed Guardian CGMS	Rt-CGM	Glucose sensors that report glucose values every 5 minutes for up to 72 hours. These readings are used with fingerstick results to detect trends and patterns in glucose levels. After a two-hour start-up period, the systems are calibrated with fingerstick measurements taken by a traditional glucose meter. After calibration, the Paradigm and Guardian REAL-Time systems provide glucose readings and updated glucose trend information for viewing every 5 minutes.	Adults, ages 18 and over, and in children and adolescents, ages 7 to 17 who have diabetes.	11/15/2005 (P980022/S011)
iPro CGM	Retro-CGM	Provides a 3-day evaluation of glucose levels. A subcutaneous sensor records glucose levels every few minutes for 3 days, and it is designed for occasional rather than everyday use. The iPro system is intended to continuously record interstitial glucose levels in diabetic individuals, but the readings are not available directly to patients in real time. The readings are available for review by physicians after the entire 72-hour recording interval.		06/19/2007 (P980022/S020)
DexCom STS-7/DexCom Seven	Rt-CGM	Glucose sensor that reports glucose values every 5 minutes for up to 72 hours. These readings are used	Individuals aged 18 and over, with	3/24/2006

Plus Continuous Glucose Monitoring System		with fingerstick results to detect trends and patterns in glucose levels. After a 2 hour start-up period, the STS System is calibrated with 2 finger-stick measurements taken by a traditional glucose meter. Originally marketed as the Dexcom STS.	diabetes	(P050012) 5/31/2007 (P050012/S001)
MiniMed Paradigm REAL-Time System	SAP	Designed to be used with an external insulin pump and is indicated for continuous or periodic monitoring of glucose levels in interstitial fluid, to detect episodes of unacceptably low and high blood glucose	Adults, ages 18 and over, and in children and adolescents, ages 7 to 17 who have diabetes.	03/8/2007 (P980022/SO15)
GlucoWatch Automatic Glucose Biographer	Retro-CGM	The GlucoWatch was the first noninvasive CGM system to be approved by the FDA. However, marketing of this device was terminated in 2007 due to problems with accuracy and skin irritation (Hayes, 2015)		03/22/2001 (P990026) 08/26/02 (P990026/S0008)
Medtronic MiniMed CGMS ® System Gold ®	Retro-CGM	Provides up to 288 glucose measurements every 24 hours. Can continuously measure glucose for up to 72-hours. The CGMS System Gold sensor is typically inserted into the subcutaneous tissue in the abdomen and worn for one to three days. A Holter-style monitor stores continuous glucose data measured by the sensor at five-minute intervals. This data can be downloaded into a computer and reports can be easily printed for retrospective analysis (Block, 2005)		1999 (exact date not found)
MiniMed Continuous Glucose Monitoring System (CGMS)	Retro-CGM	a monitor; subcutaneous glucose sensing device; connecting cable; and Com-Station, which allows data stored in the monitor to be downloaded to a personal computer.		07/14/1999 (P980022)

Abbreviations: Rt-CGM – Real-time Continuous Glucose Monitor; Retro-CGM – Retrospective Continuous Glucose Monitor; SAP – Sensor Augmented Pump; SMBG – Self-Monitoring Blood Glucose

Appendix D: *Medicaid Coverage Criteria for Continuous Glucose Monitors (2016)*

Massachusetts DME Policy Guidelines

DME and Oxygen Payment and Coverage Guideline Tool V.26

Code	PA	Description	Requirements & Limits
A9276	Yes	Sensor, invasive (e.g. subcutaneous), disposable, for use with interstitial continuous glucose monitoring system.	1 unit = each, 31 per month. (1 day supply)
A9277	Yes	Transmitter, external for use with interstitial continuous glucose monitoring system.	1 unit = each. 1 per 5 years.
A9278	Yes	Receiver (monitor), external for use with interstitial continuous glucose monitoring system.	1 unit = each. 1 per 5 years.

DME Program Regulations (3/5/10)

409.413: Covered Services

(A) MassHealth covers medically necessary DME that can be appropriately used in the member's home, and in certain circumstances described in 130 CMR 409.415 for use in facilities. All durable medical equipment must be approved for home use by the federal Food and Drug Administration (FDA). DME that is appropriate for use in the member's home may also be used in the community. (B) MassHealth covers the DME listed in Subchapter 6 of the Durable Medical Equipment Manual. Providers may request prior authorization for medically necessary DME if the corresponding service code is not listed in Subchapter 6. Covered DME includes, but is not limited to

(8) glucose monitors and diabetic supplies

Minnesota Diabetic Equipment and Supplies (1/6/2014)

Continuous Blood Glucose Monitoring

Code: A9276-A9278

Continuous blood glucose monitoring systems may be obtained from a medical supply provider or pharmacy.

Authorization

Authorization is always required for codes A9277 and A9278

Authorization is not required for code A9276

Criteria

Continuous glucose monitoring does not replace traditional home blood glucose monitoring, but may be approved as an adjunct for individuals with type-1 diabetes with a history of severe hypoglycemia less than 50 mg/dL with unawareness due to age or cognitive function. Documentation must show frequent self-monitoring and appropriate modifications to insulin regimen.

Oregon Coverage Guidance: Continuous Glucose Monitoring in Diabetes Mellitus (5/9/2013)

Continuous blood glucose monitoring with real-time or retrospective continuous glucose monitoring systems should only be covered for Type-1 diabetes mellitus patients for whom insulin pump management is being considered, initiated, or utilized and who also have one of the following:

- HbA1c levels greater than 8.0% despite compliance with therapy, or
- A history of recurrent hypoglycemia. Real-time and retrospective continuous glucose monitoring systems should not be covered for Type-2 diabetes mellitus patients

Texas Provider Manuals

Texas DME Provider Manual (February 2016)

2.2.11.4 Blood Glucose Monitors

Invasive continuous glucose monitoring (CGM) is used for diagnostic purposes to assist the clinician in establishing or modifying the client's treatment plan. A CGM device is worn up to 72 hours for the diagnostic purpose of collecting continuous blood sugar readings. These are later analyzed by the clinician.

Refer to: Subsection 9.2.24, "Continuous Glucose Monitoring (CGM)" in the Medical and Nursing Specialists, Physicians, and Physician Assistants Handbook (Vol. 2, Provider Handbooks) for additional information.

Medical and Nursing Specialists, Physicians, and Physical Assistants Handbook (February 2016)

9.2.24 Continuous Glucose Monitoring (CGM) CGM (procedure codes 95250 and 95251) is a benefit of Texas Medicaid with prior authorization. Procedure codes 95250 and 95251 are limited to once per 12 calendar months by any provider. The rental or purchase of a continuous glucose monitoring system (CGMS) is considered part of the CGM and is not reimbursed separately.

9.2.24.1 Prior Authorization for Continuous Glucose Monitoring

CGM requires prior authorization and must be prescribed by a physician performing the glucose monitoring.

CGM may be prior authorized for clients with Type I diabetes or diabetes during pregnancy, including gestational diabetes. The client must be

compliant with his or her current medical regimen, use insulin injections three or more times per day or be on an insulin pump, and have documented self-blood glucose monitoring at least four times per day. At least one or more of the following conditions must also be present:

- Frequent unexplained hypoglycemic episodes
- Unexplained large fluctuations in daily, preprandial blood glucose
- Episodes of ketoacidosis or hospitalization for uncontrolled glucose

Additional CGM services may be considered with documentation of medical necessity that indicates the client meets the criteria above and has a change in condition that would warrant a second procedure within 12 calendar months.

To avoid unnecessary denials, the physician must provide correct and complete information, including documentation of medical necessity for the requested services. The physician must maintain documentation of medical necessity in the client's medical record. The requesting provider may be asked for additional information to clarify or complete a request for the use of CGM.

Washington Home Infusion Therapy/Parenteral Nutrition Program (7/1/2015)

Continuous Glucose Monitoring (CGM)

Prior Authorization Criteria change (see WAC 182-553-400)

HCPCS Code	Description	Criteria
A9276	Sensor; Invasive (subcutaneous), disposable for use with interstitial continuous glucose monitoring system One unit = One day supply	Allowed only for clients age 18 and younger with an FDA-approved CGM device. Prior authorization and invoice required. When requesting PA, the client must: • Be diagnosed with insulin dependent diabetes mellitus. • Be followed by an endocrinologist. • Either have had one or more severe episodes of hypoglycemia or be enrolled in an Institutional Review Board-approved trial.
A9277	Transmitter; External, for use with interstitial continuous glucose monitoring system	
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system	

Closed loop systems are not covered. Verification with self-monitoring of blood glucose (SMBG) is needed prior to adjusting insulin. Do not use the CGM results to adjust insulin.

To submit a claim for the physician interpretation and report of CGM results, see procedure code 95251 (PA **not** required) in the Physician-Related Services/Healthcare Professional Services Fee Schedule online at: http://hrsa.dshs.wa.gov/RBRVS/Index.html.

Washington Health Technology Assessment Program

Glucose Monitoring (1-15-2011)

Final evidence report

Final decision

HTCC Coverage Determination

Self-Monitoring Blood Glucose (SMBG) is covered benefit

Continuous Glucose Monitoring (CGM) is a covered benefit with conditions

HTCC Reimbursement Determination

- Limitations of Coverage
  - Continuous Glucose Monitoring (CGM) is a covered benefit for diabetes mellitus (DM) patients under 19 using insulin when the following conditions are met:
    - Suffering from one or more severe episodes of hypoglycemia; or enrolled in an IRB approved trial

Washington Administrative Rules

WAC 182-553-500 (filed 6/26/15, effective 7/27/15)

Home infusion therapy and parenteral nutrition program—Coverage, services, limitations, prior authorization, and reimbursement.

(3) The agency pays for FDA-approved continuous glucose monitoring systems and related monitoring equipment and supplies with prior authorization for a client who:

(a) Either has had one or more severe episodes of hypoglycemia or is enrolled in a trial approved by an institutional review board;

(b) Is age eighteen and younger;

(c) Has a diagnosis of insulin dependent diabetes mellitus; and

(d) Is followed by an endocrinologist.

(4) Requests for supplies or equipment that exceed the limitations or restrictions listed in this section require prior authorization and are evaluated on an individual basis according to the provisions of WAC **182-501-0165** and**182-501-0169**.

Source: Accessed from Massachusetts, Minnesota, Oregon, Texas, Washington on 3/10/2016 from Medicaid websites.

Appendix D: *Private Payer Policies for Continuous Glucose Monitors (2016)*

Relevant policy language excerpted from policies identified is included below.

Aetna

Number 0070

Last Review 10/23/2015

Continuous Glucose Monitoring Devices:

Aetna considers the short-term (up to 72 hours) diagnostic use of continuous glucose monitoring devices medically necessary for persons with diabetes who have either of the following problems in controlling blood glucose level, unresponsive to conventional insulin dose adjustment:

A. Hypoglycemia unawareness; or
B. Repeated hypoglycemia and hyperglycemia at the same time each day.

For short-term (up to 72 hours) diagnostic use, no more than two continuous glucose monitoring periods are considered medically necessary within a 12-month period.

Aetna considers the long-term (greater than 72 hours) therapeutic use of continuous glucose monitoring devices medically necessary as an adjunct to fingerstick testing of blood glucose in adults aged 25 years and older with type-1 diabetes, and for younger persons with type-1 diabetes who have had recurrent episodes of severe hypoglycemia (defined as hypoglycemia (blood glucose less than 50 mg/dL) with unawareness that required assistance from another person to administer oral carbohydrate, glucagon, or other resuscitative actions) despite appropriate modifications in insulin regimen and compliance with frequent self-monitoring (at least 4 fingersticks/day). Long-term use of continuous glucose monitoring devices is considered experimental and investigational for all other indications.

Aetna considers experimental and investigational the use of continuous glucose monitors for nesidioblastosis (primary islet cell hypertrophy) and for monitoring blood glucose in nondiabetic persons following gastric bypass surgery because there is insufficient evidence of the clinical benefits of this approach for these indications.

Biostator® Artificial Pancreas:

Aetna considers the Biostator System, a device which functions as an artificial pancreas, experimental and investigational. There are insufficient data in the published peer-reviewed medical literature documenting the safety and effectiveness of the Biostator.

Artificial Pancreas Device System with Low Glucose Suspend Feature:

Aetna considers a continuous glucose monitor and insulin pump with a low glucose suspend feature (artificial pancreas device) an equally acceptable alternative to a standard insulin pump and continuous glucose monitor for medically necessary indications.

GlucoWatch® Biographer Monitor:

Aetna considers the GlucoWatch Biographer (Cygnus Inc, Redwood City, CA.), a glucose meter that is worn on the wrist, experimental and investigational.

Cigna

Coverage Policy Number 0106

Effective Date 4/15/2015

Home Blood Glucose Monitors

Continuous Glucose Monitoring System (CGMS)

Cigna covers a minimally invasive, continuous glucose monitoring system (CGMS) as medically necessary for up to three days (72 hours) under the core medical benefits of the plan for the management of difficult to control insulin-treated diabetes mellitus (e.g., hypo- or hyperglycemic episodes unresponsive to adjustments in therapy, asymptomatic nocturnal hypoglycemia) for up to six separate sessions in any given 12-month period. (CPT® code 95250, 95251)

Cigna covers a minimally invasive, continuous glucose monitoring system (CGMS) (HCPCS code A9277, A9278) as medically necessary for ANY of the following:

- long-term use in a type-1 diabetic age 25 years or older
- long-term use in a type-1 diabetic age 24 years or younger with recurrent, severe hypoglycemic events (i.e., blood glucose < 50 mg/dL) despite appropriate modifications in insulin therapy and compliance with frequent self-monitoring of blood glucose (i.e., at least four times daily)
- long-term use in a type-2 diabetic with recurrent, severe hypoglycemic events (i.e., blood glucose < 50mg/dL) despite appropriate modifications in insulin therapy, and compliance with frequent self-monitoring of blood glucose (i.e., at least four times daily)

when ANY of the following criteria have been met:

- history of diabetic ketoacidosis
- positive autoantibody test as evidenced by any one of the following:
    - islet cell cytoplasmic autoantibodies [ICA]
    - glutamic acid decarboxylase autoantibodies [GADA]

- insulinoma-associated-antigen 2 autoantibodies [IA-2A])
- fasting C-peptide level ≤ 110% of the lower limit of normal of the laboratory's measurement method AND a concurrently obtained fasting glucose ≤ 225 mg/dL
- renal insufficiency with a creatinine clearance (actual or calculated from age, gender, weight and serum creatinine) ≤ 50 ml/minute AND a fasting C-peptide level ≤ 200% of the lower limit of normal of the laboratory's measurement method

Replacement of a Continuous Glucose Monitoring System and Components

Cigna covers the replacement of an existing continuous glucose monitoring system or component as medically necessary for an individual with successfully managed type-1 or type-2 diabetes mellitus on a continuous glucose monitor when BOTH of the following criteria are met:

- documentation confirming that the monitor/component is malfunctioning, is no longer under warranty and cannot be repaired
- evidence of an evaluation by the health care provider managing the diabetes within the last six months that includes a recommendation supporting continued use of a continuous glucose monitor

Not Covered

Cigna does not cover ANY of the following because each has not demonstrated an improvement to health outcomes and is therefore, considered not medically necessary and/or a convenience item.

- additional software or hardware required for downloading data to a device such as personal computer, smart phone, or tablet to aid in self-management of diabetes mellitus
- combination devices that include a home blood glucose monitor combined with a cellular telephone or other device not specifically indicated for the management of diabetes mellitus (e.g., blood pressure monitor, cholesterol screening analyzer)
- remote glucose monitoring device (e.g., mySentry)

Covered when medically necessary:

CPT® * Codes	**Description**
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum 72 hours; interpretation and report
HCPCS Codes	Description
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, one unit = 1 day supply

A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system

UnitedHealthcare

Policy Number 2015T0347R

Effective Date April 22, 2015

Continuous Glucose Monitors with or without Combined Insulin Pumps

Short-term (3-7 days) continuous glucose monitoring by a healthcare provider for diagnostic purposes is proven and medically necessary for patients with diabetes.

Long-term continuous glucose monitoring for personal use at home is proven and medically necessary as a supplement to self-monitoring of blood glucose (SMBG) for patients with type-1 diabetes who meet EITHER of the following criteria AND have demonstrated adherence to a physician ordered diabetic treatment plan:

- Have been unable to achieve optimum glycemic control as defined by the most current version of the American Diabetes Association (ADA) Standards of Medical Care in Diabetes; or
- Have experienced hypoglycemia unawareness and/or frequent episodes of hypoglycemia

Long-term continuous glucose monitoring for personal use at home is unproven and not medically necessary for patients with type-2 diabetes or gestational diabetes. There is insufficient evidence that the use of long-term continuous glucose monitoring leads to improvement of glycemic control in patients with type-2 or gestational diabetes.

For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 19th edition, 2015, Continuous Glucose Monitoring ACG:A-0126 (AC).

Remote Glucose Monitoring

Remote glucose monitoring is unproven and not medically necessary for managing patients with diabetes. There is insufficient evidence in the clinical literature to conclude that remote glucose monitoring demonstrates improvement in clinical outcomes.

CPT® Code	Description
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording

95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report

HCPCS Code	Description
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
A9275	Home glucose disposable monitor, includes test strips
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply
A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system

HCPCS Code	Description
E1399	Durable medical equipment, miscellaneous NOTE: The i-port device is not durable medical equipment (DME) nor does it have a listed code
S1030	Continuous noninvasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code)
S1031	Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use CPT code)
S1034	Artificial Pancreas Device System (e.g., Low Glucose Suspend [LGS] Feature) Including Continuous Glucose Monitor, Blood Glucose Device, Insulin Pump And Computer Algorithm That Communicates With All Of The Devices
S1035	Sensor; Invasive (e.g., Subcutaneous), Disposable, For Use With Artificial Pancreas Device System
S1036	Transmitter; External, For Use With Artificial Pancreas Device System
S1037	Receiver (Monitor); External, For Use With Artificial Pancreas Device System

Sources: Aetna®, Cigna®, and UnitedHealthcare® accessed 3/10/2016. Text excerpted from policies on websites.

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Suggested citation: Scantlan, J., & Harrod, C. (2016). *Continuous glucose monitoring for individuals with type 1 and type 2 diabetes*. Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

Conflict of Interest Disclosures: No authors have conflicts of interest to disclose. All authors have completed and submitted the Oregon Health & Science University form for Disclosure of Potential Conflicts of Interest, and none were reported.

Funding/Support: This research was funded by the Center for Evidence-based Policy's Medicaid Evidence-based Decisions Project at Oregon Health & Science University.

Spinal Cord Stimulation Assessing Signals for Update

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Aug 29, 2016

Contents

Previous Coverage Decision

A Comparative Effectiveness Review (CER) titled: SPINAL CORD STIMULATION, was originally released in July 2010 by the Health Technology Clinical Committee and summarized below.

Health Technology Background

The Spinal Cord Stimulation topic was selected and published in December 2009 to undergo an evidence review process. Spinal Cord Stimulation (SCS) is an alternative treatment proposed for patients with chronic neuropathic pain who have not responded to conventional therapies such as medication, physical and/or psychological therapy, and in some case, re-operation. Current best evidence is available primarily from four trials on 375 patients; which are rated at a Level 1 or 2 (good quality), which is a better level of evidence than some interventions. However, total patient sample size is small, comparators were weak or inappropriate, reported outcomes are mostly subjective and not consistently reported, industry funding and management may have an impact, and no trial included a sham stimulation/procedure arm. The overall body of evidence was inconsistent, with several trials showing benefits on some outcomes at generally shorter follow up periods and others showing no difference. SCS is an implanted, long term treatment, but no evidence exists on either long term efficacy or safety.

The committee agreed that SCS is less safe than alternatives, is an invasive procedure, and has many adverse events. While conventional medical management is not invasive, so would generally have a lower risk profile, re-operation is also a comparator and had less complications. SCS device related complications can be serious and include dural punctures, amplitude by bodily movements; paresthesia in other body parts, pain, disturbed urination, lead fracture, loss of effect, infection. Indications for SCS (FDA): Chronic intractable pain in the trunk and/or limbs including unilateral or bilateral pain associated with FBSS and intractable low back and leg pain, and for some devices: CRPS, radicular pain syndrome or radiculopathies resulting in pain, post-laminectomy pain, unsuccessful disc surgery, degenerative disc disease or herniated disc pain refractory to conservative or surgical interventions, peripheral causalgia, epidural fibrosis, arachnoiditis or lumbar adhesive arachnoiditis, and multiple back surgeries. Potential patients should undergo a period of trial stimulation prior to permanent SCS implantation. Contraindications for SCS (FDA): Failed trial stimulation due to ineffective pain relief; poor surgical risks; pregnancy; active general infections or multiple illnesses; inability to operate the SCS system; and cardiac pacemakers (with specific exceptions and precautions) or cardioverter defibrillators.

In June 2010, the HTA posted a draft and then followed with a final report from a contracted research organization that reviewed publicly submitted information; searched, summarized, and evaluated trials, articles, and other evidence about the topic. The comprehensive, public and peer reviewed Spinal Cord Stimulation report is 164 pages, and identified a relatively large amount of literature.

An independent group of eleven clinicians who practice medicine locally meet in public to decide whether state agencies should pay for the health technology based on whether the evidence report and other presented information shows it is safe, effective and has value. The committee met on August 20, reviewed the report, including peer and public feedback, and heard public and agency comments. Meeting minutes detailing the discussion are available through the HTA program or online at http://www.hta.hca.wa.gov under the committee section.

Committee Conclusions

Having made findings as to the most significant and relevant evidence regarding health outcomes, key factors and identified evidence related to those factors, primarily based on the evidence based technology assessment report, the committee concludes:

(1) Evidence availability and technology features

The committee concludes that the best available evidence on Spinal Cord Stimulation has been collected and summarized.

- Spinal Cord Stimulation (SCS) is an alternative treatment proposed for patients with chronic neuropathic pain who have not responded to conventional therapies such as medication, physical and/or psychological therapy, and in some case, re-operation.
- Current best evidence is available primarily from four trials on 375 patients; which are rated at a Level 1 or 2 (good quality), which is a better level of evidence than some interventions. However, total patient sample size is small, comparators were weak or inappropriate, reported outcomes are mostly subjective and not consistently reported, industry funding and management may have an impact, and no trial included a sham stimulation/procedure arm. The overall body of evidence was inconsistent, with several trials showing benefits on some outcomes at generally shorter follow up periods and others showing no difference.
- SCS is an implanted, long term treatment, but no evidence exists on either long term efficacy or safety.

(2) Is it safe?

The committee concludes that the comprehensive evidence indicates that Spinal Cord Stimulation is less safe than alternative treatments. Key factors to the committee's conclusion included:

- The committee agreed that SCS is less safe than alternatives, is an invasive procedure, and has many adverse events. While conventional medical management is not invasive, so would generally have a lower risk profile, re-operation is also a comparator and had less complications. SCS device related complications can be serious and include dural punctures, amplitude by bodily movements; paresthesia in other body parts, pain, disturbed urination, lead fracture, loss of effect, infection.
- The committee agreed that safety was a significant factor: the number of trial reported complications ranged from 8 to 100%. Device related complication requiring revision ranged from 25% to 38% of patients in short term and 42% to 60% in up to 5 years (not including 54% of patients undergoing pulse generator replacements due to battery life).
- The committee agreed that there were currently no reported mortality rates, but that the FDA data was not available and the small sample size is likely underpowered to detect.
- The committee agreed that the removal rate could be considered an efficacy or safety issue, but the rates ranging from 4% to 17% were concerning, especially considering that trial stimulation is done first on all patients.

(3) Is it effective?

The majority of the committee concludes that the comprehensive evidence about Spinal Cord Stimulation effectiveness is unproven.

- The committee agreed that the studies had serious limitations in design, low patient sample sizes, and weak or inadequate comparators. Additionally, placebo effects of a new intervention for patients with chronic pain who have already failed multiple therapies is a serious concern and no study involved sham stimulation or procedures and outcome measures were generally subjective.
- The committee found that evidence overall on important patient outcomes was limited. For all outcomes, there is no evidence of longer term improvement, particularly important when there are significant risks (including 1/3 revision and high removal rate) and the device is intended for permanent implant.
- Given the serious limitations of the studies, the committee agreed that, at best, weak evidence exists that SCS may provide temporary improvement of pain in some patients, but there is no evidence of mid or long term pain improvement.
- While pain is a critical patient outcome, evidence about other important patient outcomes was either not available or not consistent with the pain findings.
    - For instance, for reduction in pain medication in short term: Kumar and Turner found no difference, while North found SCS patients did have reduction.
    - For functional improvements, 1 trial found short term functional improvement, but 2 others did not; and there was no reliable evidence of functional improvement at mid (or long) term.

- For all other outcomes, including improvement in quality of life, there is no reliable evidence of effect.

(4) Evidence about the technology's special populations, patient characteristics and adjunct treatment

The committee agreed that no compelling evidence exists to differentiate sub groups or special populations.

- The committee agreed with the evidence based report that there is inadequate evidence to identify characteristics that either enhance or reduce the efficacy of SCS such as age, sex, workers' compensation or other disability payments, duration of pain, pain intensity, time since first lumbar surgery, number of prior operations for pain, pain location, laterality of pain, allodynia or hypoesthesia at baseline, McGill Pain Questionnaire or the Minnesota Multiphasic Personality Inventory (MMPI)

(5) Is the technology cost-effective?

- The committee concludes that SCS is unproven to be cost effective.
- The committee agreed that the cost of SCS is substantial, averaging $27,000 per patient.
- The committee agreed that overall value cannot be ascertained without evidence of net benefit of effectiveness and reduced harm. Reliable cost-effectiveness analysis cannot be performed.

Committee Decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and agency and state utilization information. The committee concluded that the current evidence on Spinal Cord Stimulation demonstrates that there isn't sufficient evidence to cover the use of Spinal Cord Stimulation for chronic neuropathic pain. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Based on these findings, the committee voted 8 to 1 to not cover Spinal Cord Stimulation.

The committee reviewed the Clinical guidelines and Medicare decision. The Medicare decision was did not cite evidence and was decided prior to any of the studies reviewed by the committee. The guidelines recommendations conflict and not all have reviewed the latest trials included in this report.

1. Purpose of Report

A prior update report was completed in January 2014. The purpose of this literature update is to determine whether there is sufficient evidence published after the last update to conduct a re-review of this technology.

2. Methods

2.1 Literature Searches

We conducted a limited literature search for articles published between Aug 1, 2013 and Aug 21, 2016 using the identical search strategy used for the original report. This search included four main databases: PubMed, Medline, Cochrane Library, and EMBASE. Appendix A includes the search methodology for this topic.

2.2 Study selection

In general, we used the same inclusion and exclusion criteria as the original CER.

2.3 Compilation of Findings and Conclusions

For this assessment we abstracted the data from the included studies and constructed a demographics table, Table 1. We also constructed a summary table that included the key questions, the original conclusions, the prior update data, new sources of evidence, new findings, and conclusions based on available signals, Table 2. To assess whether the conclusions might need updating, we used an algorithm based on a modification of the Ottawa method, Figure 1.

3. Results

3.1 Search

A systematic review was undertaken for articles published between Aug 1, 2013 and Aug 21, 2016. We used search strategies to identify articles from MEDLINE, EMBASE and the Cochrane Library. We used key words to detect articles that used the terms “spinal cord stimulation”, “spinal cord stimulator”, or “spinal cord stimulation”, Appendix A. Among the articles describing the efficacy and/or safety of spinal cord stimulation, we evaluated the full text to determine if the studies met our inclusion criteria. Full text of potential articles meeting the inclusion criteria by both methods were reviewed to obtain the final collection of included studies, Figure 2.

The literature search identified 411 titles. After title and abstract review, we further reviewed the full text of 19 journal articles. The remaining 392 titles were rejected because they were case reports, commentary, or did not include topics of interest. Among the 19 articles that went on to full text review, 13 were rejected because subjects did not meet the inclusion criteria and/or did not include a comparison of interest, Appendix B. No new systematic reviews with quantitative synthesis of relevant literature were identified.

3.2 New SCS applications

Since our report, we identified two new strategies for electrical waveform delivery for SCS; high frequency SCS (HFSCS) (at 10,000 Hz) and burst SCS. Traditional SCS has a pulse width of 400 μsec and a stimulation rate of 40 Hz.[1] The objective of traditional (tonic) SCS is to induce a paresthesia that overlaps with the painful region.

High-frequency stimulation delivers the energy at a higher frequency (most studies use 10,000 Hz), while burst stimulation delivers 40 Hz bursts of 5 spikes at 500 Hz. Both methods of stimulation provide modulation of the nervous system without the patient perceiving paresthesia. This is done by reducing the amplitude to subthreshold levels.

3.3 Studies identified (Table 1)

No systematic reviews were identified that contained new RCTs with a quantitative analysis of results (meta-analysis). Therefore, we identified relevant trials and summarize them below.

Two small trials compared SCS with a control group. de Vos et al[2] randomized 60 patients to receive SCS (n = 40) or conventional pain treatment (n=20) in those with painful diabetic neuropathy. The mean age was 59.5 years and 63% were male. The follow-up period was 6 months. The investigators reported that 60% of the SCS group and 5% of the control group achieved >50% pain reduction at follow-up (p<.001). The mean reduction in VAS pain (0-100 scale) over baseline was 42 for the SCS group and 0 for the control (p<.001). Adverse events included pain due to the implanted pulse generator (n=2) and electrode lead migration (n=1); perceived incomplete overlap of the paresthesia with the painful area during trial stimulation requiring placement of a second electrode lead (n=2); infection during trial stimulation (n=1) that was successfully resolved and followed by a permanent implantation; and coagulopathy, which complicated the implantation procedure and prolonged hospitalization (n=1). Limitations of this study include an open label design, a lack of a placebo control, no functional or quality of life outcomes, and vagueness of allocation concealment.

Slangen et al[3] randomized 36 patients to receive SCS plus best medical treatment (n = 22) or best medical treatment alone (n=14) in those with painful diabetic neuropathy. The mean age was 56.9 years and 67% were male. The follow-up period was 6 months. The investigators reported that 41% of the SCS group and 0% of the control group achieved >50% pain reduction during the day, and 36% vs. 7% at night at follow-up (p<.001). Patient's Global Impression of Change for pain and for sleep were also better in the SCS group compared with control: 55% and 36% vs. 0% and 0%, respectively, p<.01). There were two serious adverse events in this trial. One patient sustained a dural puncture during implantation of a lead for test stimulation, followed by subdural hematoma and death; and one patient had an infection of the SCS system 6 weeks after implantation with a slow but incomplete recovery. Limitations of this study include an open label design, a lack of a placebo control, no functional or quality of life outcomes,and vagueness of allocation concealment.

Three small industry sponsored cross-over RCTs compared either HFSCS or burst SCS to placebo stimulation. Schu et al[4] treated 20 patients with failed back surgery syndrome (FBSS) and a preexisting SCS system. Each received three treatment allocations in random order for a period of one week: tonic SCS (500-Hz), burst SCS, and placebo stimulation. The mean age was 58.6 years, and 35% were male. The investigators reported that burst SCS reduced pain intensity as measured by the numerical rating scale (NRS) after one week compared with placebo: 4.7 ±2.5 vs. 8.3 ±1.1, p<.05. Pain quality as measured by the short form McGill Pain Questionnaire (SFMPQ) was also better in the burst vs. placebo group: 19.5 ±10.5 vs. 33.5 ±11.8, p<.05. Eighty percent of the patients preferred burst SCS over placebo, tonic or conventional SCS, p= .0004. Limitations of this study include a very short follow-up of only 1 week, no wash out period between cross-over periods, and a study population with stable benefit from conventional SCS (i.e., results may not be generalizable to patients naïve to stimulation).

Likewise, de Ridder et al[5] treated 15 patients that had a preexisting SCS system, 12 who had FBSS. Each received three treatment allocations in random order for a period of one week: traditional tonic SCS, burst SCS, and placebo stimulation. The mean age was 54.1 years, and 27% were male. The investigators reported that burst SCS reduced axial, limb and general pain as measured by the percent change over baseline in VAS (0-100 mm) after one week compared with placebo: 51.3%, 52.7%, 55.0%

vs. 18.9%, 11.7% and 10.9%, respectively, p<.05 for each outcome. Attention to pain and changes in pain as measured by the Pain Vigilance and Awareness Questionnaire (PVAQ) were also better in the burst vs. placebo group: 7.6% and 10.0% vs. 3.3 and 3.2%, respectively, p<.05 for each outcome. Limitations of this study include a very short follow-up of only 1 week, no wash out period between cross-over periods, and a study population with stable benefit from conventional SCS (i.e., results may not be generalizable to patients naïve to stimulation). Furthermore, the principle author holds a patent for burst stimulation.

Perruchoud et al[6] treated 33 of 38 study participants that had chronic low back pain and used a preexisting SCS system. Each received their current (conventional) SCS followed by either HFSCS (10,000 Hz) or placebo stimulation selected randomly, followed by conventional SCS followed by either HFSCS or placebo, whichever treatment was not given earlier. The period lasted one week. The mean age was 54.2 years, and 48% were male. The primary outcome measure was the Patient's Global Impression of Change (PGIC). The investigators reported no difference between HFSCS and placebo with respect to the proportion of PGIC reporting at least "minimal improvement", (42.4% vs. 30.3%), p = .30. There were no differences between treatment groups in VAS pain nor EQ-5D. The authors note a significant "period effect"; patients who had a either HFSCS or placebo first did better than those who had HFSCS or placebo second. Limitations of this study include a very short follow-up of only 2 weeks, no wash out period between cross-over periods, and a study population with stable benefit from conventional SCS (i.e., results may not be generalizable to patients naïve to stimulation).

One cost effectiveness and cost utility study of SCS in patients with FBSS was reported.[7] The authors used a before-after design where patients with predominant leg pain refractory to conventional medical treatment (CMM) expecting to receive SCS were recruited in 9 Italian centers and followed up to 24 months after SCS. They collected data on clinical status, Health-Related Quality-of-Life (HRQoL) and on direct and indirect costs retrospectively before and prospectively after the SCS intervention. Costs were quantified in € 2009, adopting the National Health Service's (NHS) and societal perspectives. They included 80 patients. The mean age was 58 years, and 40% were male. The utility gained during the 12-24 month post-SCS period corresponds to a QALY increase of 0.173, generating a cost per QALY gained of €47,000 and of €38,372 from the NHS and societal points of view, respectively. The authors conclude that the cost-utility acceptability curve suggests that, if decision makers' willingness to pay per QALYs was €60,000, SCS implantation would be cost-effective in 80% and 85% of cases, according to the NHS's and societal point of views, respectively.

4. Conclusions: Identifying signals for re-review

Table 2 shows the original key questions, the conclusions of the original report, the new sources of evidence, the new findings, and the conclusions of Spectrum Research, Inc. (SRI) with respect to the criteria that identify a trigger for an update.

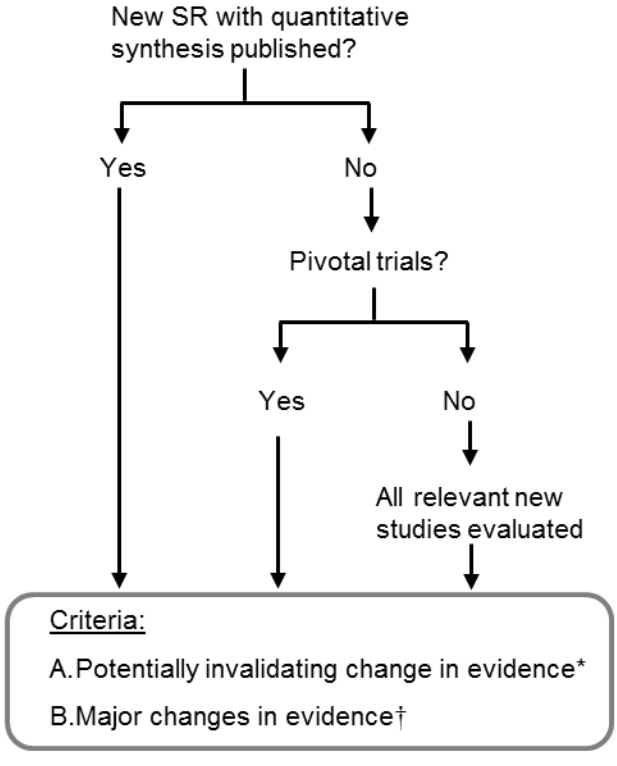
4.1 Key Question 1: With respect to efficacy, two studies compared SCS to conventional treatment in patients with diabetic neuropathy. Both found a short term pain improvement in favor SCS. There were no assessments of function or quality of life. Both studies report complications, some serious, to include serious infection and dural puncture leading to death. Three studies looked at new applications of SCS, high frequency SCS and burst stimulation. All were short term (1 or 2 weeks) cross-over studies in patients who were already receiving traditional SCS. While burst stimulation shows some promise in these early cross-over studies, longer follow-up studies that compare burst stimulation in parallel arms to both non-stimulation therapy and placebo are needed in patients naïve to stimulation. Unfortunately, there are no current studies registered in ClinTrials.gov making these assessments, Appendix C. The five new RCTs evaluated in this signal report do not invalidate the previous evidence (criteria A-1 or A3), nor provide major changes in the evidence (criteria B-1 – B4).

4.2 Key Question 2: With respect to safety of spinal cord stimulation, data from two studies continue to underscore that SCS is not without complications and do not invalidate the previous evidence (criteria A-2

4.3 Key Question 3: There is no new evidence with respect to differential efficacy or safety of SCS in sub populations.

4.4 Key Question 4: A new cost-utility study does not invalidate the previous evidence (criteria A-1 or A-3), nor provide major changes in the evidence (criteria B-1).

Figure 1. Algorithm using a modified version of the Ottawa Method of identifying signals for SR updates



*A-1. Opposing findings: Pivotal trial or SR including at least one new trial that characterized the treatment in terms opposite to those used earlier

A-2. Substantial harm: Pivotal trial or SR whose results called into question the use of the treatment based on evidence of harm or that did not proscribe use entirely but did potentially affect clinical decision making

A-3. Superior new treatment: Pivotal trial or SR whose results identified another treatment as significantly superior to the one evaluated in the original review, based on efficacy or harm.

†B-1. Important changes in effectiveness short of "opposing findings"

B-2. Clinically important expansion of treatment

B-3. Clinically important caveat

B-4. Opposing findings from discordant meta-analysis or nonpivotal trial

Figure 2. Flow chart showing results of literature search

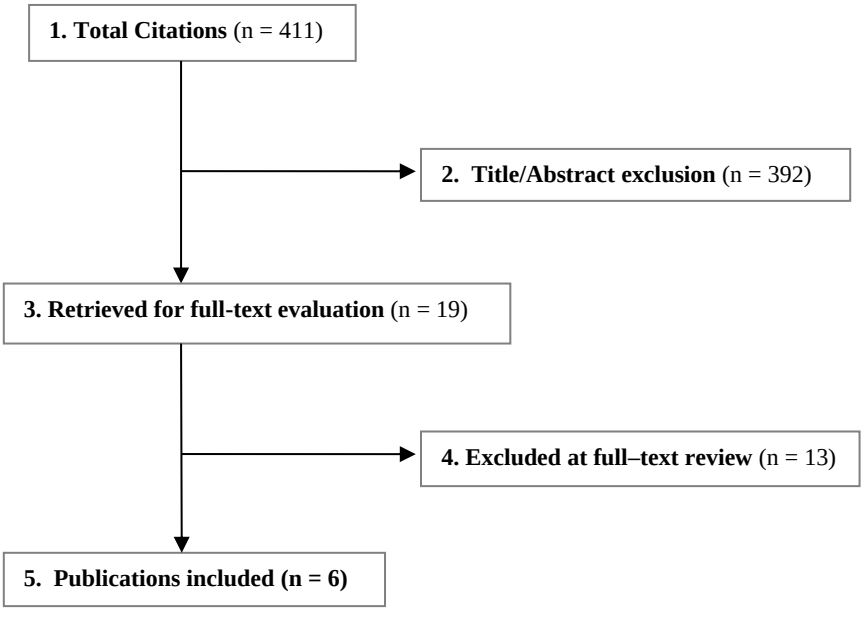


Table 1. Study characteristics of included studies

Author (Year) Study type	Demographics	Results	Conclusion	Limitations Conflict of interest
Schu (2013) cross-over RCT	N = 20 (all receiving conventional tonic SCS at time of enrollment) Male: 35% Age: 58.6 ±10.2 F/U: 1 week <u>Diagnosis</u>: FBSS <u>Intervention vs. control</u>: • Burst stim (5 pulses at 500 Hz, 40x/sec) vs. • Tonic stim (500 Hz) vs. • Placebo	<u>NRS pain intensity (0-10, 10 = worse pain):</u> • Burst Stim: 4.7 ±2.5 • 500-Hz Tonic Stim: 7.1 ±1.9 • Placebo Stim: 8.3 ±1.1 *p* <.05 burst vs. tonic, burst vs. placebo <u>Pain quality (SFMPQ):</u> • Burst Stim: 19.5 ±10.5 • 500-Hz Tonic Stim: 28.6 ±10.2 • Placebo Stim: 33.5 ±11.8 *p* <.05 burst vs. tonic, burst vs. placebo <u>Patient preference:</u> • Burst Stim: 80% • 500-Hz Tonic Stim: 10% • Placebo Stim: 0% • Conventional tonic Stim: 10% *p* = .0004 burst vs. tonic, burst vs. placebo, burst vs. conventional	Overall, burst stimulation resulted in significantly better pain relief and improved pain quality in the short term compared with 500-Hz tonic stimulation and placebo stimulation and was preferred by the majority of patients.	• Very short follow-up of only 1 week • No wash out period between cross-over • Trial aimed to compare effect of burst stimulation in patients with stable benefit from conventional SCS; may not be generalizable to patients naïve to stimulation Some authors are consultants for St. Jude Medical, Inc. receiving payment for educational presentations, some receive fellowship training or grants. St. Jude Medical, Inc. owns the rights to the burst SCS
De Ridder (2013) cross-over RCT	N = 15 Male: 27% Age: 54.1 (39-68, range) F/U: 1 week <u>Diagnosis</u>: FBSS (80%) Other (20%) <u>Intervention vs. control</u>: • Burst stim (5 pulses at 500 Hz, 40x/sec) vs. • Tonic stim (40-50 Hz) vs. • Placebo	<u>Axial, limb, general pain (%Δ from baseline, 0-100 mm):</u> • Burst Stim: 51.3%, 52.7%, 55.0% • Tonic Stim: 30.3%, 51.5%, 30.9% • Placebo Stim: 18.9%, 11.7%, 10.9% Axial: *p*<.05 burst vs. placebo Limb: *p* <.05 burst vs. placebo, tonic vs. placebo General: *p* <.05 burst vs. placebo, burst vs. tonic, tonic vs. placebo <u>PVAQ attention to pain, changes in pain:</u> • Burst Stim: 7.6%, 10.0% • Tonic Stim: 5.0%, 3.9% • Placebo Stim: 3.3%, 3.2% Attention to pain & to changes in pain: *p* <.05 burst vs. placebo, burst vs. tonic <u>Pain now, least pain, worst pain</u>	In comparison with placebo, burst, corrected for multiple comparisons, was significantly better for all measurements. The differences between tonic and burst stimulation are likely attributable to a more-selective modulation of the medial pain pathways by burst stimulation, as shown by the activation of the dorsal anterior cingulate cortex.	• Very short follow-up of only 1 week • No wash out period between cross-over • No description of random process • Trial aimed to compare effect of burst stimulation in patients with stable benefit from conventional SCS; may not be generalizable to patients naïve to stimulation Principle author holds a patent for burst stimulation

Author (Year) Study type	Demographics	Results	Conclusion	Limitations Conflict of interest
		• Burst Stim: 49.8%, 73.2%, 36.0% • Tonic Stim: 26.0%, 45.8%, 12.6% • Placebo Stim: 12.8%, 21.7%, 0.6% Pain now: p <.05 burst vs. placebo, tonic vs. placebo Least pain: p <.05 burst vs. placebo, tonic vs. placebo, burst vs. tonic Worst pain: p <.05 burst vs. placebo, burst vs. tonic		
Perruchoud (2013) cross-over RCT	N = 33* Male: 48% Age: 54.2 ±10.7 F/U: 2 weeks <u>Diagnosis</u>: Chronic LBP <u>Intervention vs. control</u>: • HFSCS (10,000 Hz) vs. • Placebo	<u>PGIC responders reporting at least "minimal improvement":</u> • HFSCS: 42.4% • Placebo Stim: 30.3% Mean benefit of HFSCS vs. placebo = 11.2% (95% CI: -10.1% to 32.5%), p = .30) <u>EQ-5D, VAS pain:</u> p >.05 for both	HFSCS was equivalent to placebo for all outcomes. There was an obvious "period effect" in the sense that effect of HFSCS and sham seems to be equal and only the order in the sequence, not the nature of the treatment, appears to dictate the effect.	• Very short follow-up of only 2 weeks • No wash out period between cross-over • Trial aimed to compare effect of HFSCS in patients with stable benefit from conventional SCS, may not be generalizable to patients naïve to stimulation. Funded and technical support for programming by Medtronic. Some authors consult for and are members of advisory boards for Medtronic, receiving consulting fees, honoraria, speaking and travel fees.
de Vos (2014) RCT	N = 60 Male: 63% Age: 59.5 ± 11.2 F/U: 6 months <u>Diagnosis:</u> Painful diabetic neuropathy (PDN) <u>Intervention vs. control</u>: • SCS (n = 40)	<u>Absolute VAS reduction over baseline</u> • SCS: 42 ± 31 • Control: 0 ± 20 p <.001 SCS vs. Control <u>Relative VAS reduction</u> • SCS: 55% ± 41% • Control: 0% ± 5% p <.001 SCS vs. Control <u>>50% pain reduction</u> • SCS: 60%	Overall, SCS reduces pain significantly and improves the quality of life in patients with refractory PDN in the lower extremities compared to conventional pain treatment.	• Random allocation concealment unclear • Open label design • Lack of placebo • No functional or quality of life outcomes One author received teaching fees from St. Jude Medical and is a paid consultant for Biolab Technology.

Author (Year) Study type	Demographics	Results	Conclusion	Limitations Conflict of interest
	• Conventional pain treatment (details NR) (n = 20)	• Control: 5% *p* <.001 SCS vs. Control Adverse events unrelated to procedure • SCS: 10% (4/40) • Control: 30% (6/20) Adverse events related to procedure† • SCS: 15% (6/40) • Control: 0%		
Slangen (2014) RCT	N = 36 Male: 67% Age 56.9 ±10.7 F/U: 6 months Diagnosis: Painful diabetic neuropathy (PDN) Intervention vs. control: • SCS +BMT (n = 22) • BMT alone) (n = 14)	>50% pain reduction (day, night) • SCS: 41%, 36% • Control: 0%, 7% *p* <.001, <.01 SCS vs. Control (day, night) PGIC for pain, for sleep • SCS: 55%, 36% • Control: 0%, 0% *p* <.001, <.01 SCS vs. Control (pain, sleep) Success‡ • SCS: 59% • Control: 7% *p* <.01 SCS vs. Control Adverse events unrelated to procedure • SCS: 10%§ • Control: 0%	Treatment success was shown in 59% of patients with painful diabetic peripheral neuropathy who were treated with SCS over a 6-month period, although this treatment is not without risks.	• Random allocation concealment unclear • Open label design • Lack of placebo • No functional or quality of life outcomes Funding from Medtronic who provided a grant for the employment of one of the investigators.
Zucco (2015) Cost effectiveness, cost utility using a before/after study design	N = 80 Male: 40% Age 58 ±13 F/U: 24 months Diagnosis: FBSS Intervention: SCS + CMM Comparator:	**Cost-effectiveness results (SCS + CMM versus CMM):** NHS perspective: • ICUR: €47,000/QALY • ICER: €3,222/NRS Society perspective: • ICUR: €38,372/QALY • ICER: €2,631/NRS	The cost-utility acceptability curve suggested that if decision makers' willingness to pay per QALYs was €60,000, SCS implantation would be cost-effective in 80% and 85% of cases, according to the NHS's and societal point of views, respectively	• Before – after study design • Pre SCS data collected retrospectively Funded by Medtronic Italy.

Author (Year) Study type	Demographics	Results	Conclusion	Limitations Conflict of interest
	CMM alone <u>Analysis</u>: • NHS and Society perspective • ICER, ICUR • Primary outcomes: Pain NRS for ICER, EQ-5D for ICUR			

Abbreviations: BMT: best medical therapy; CMM: conventional medical management; EQ-5D: EuroQol five dimensions questionnaire; FBSS: failed back surgery syndrome; F/U: follow-up; HFSCS: high frequency spinal cord stimulation; ICER: incremental cost-effectiveness ratio; ICUR: incremental cost-utility ratio; KQ: key question; LBP: Low back pain; NA: not applicable; NHS: National Health Service; NRS: Numerical rating scale; NS: not statistically significant; PGIC: Patient's Global Impression of Change; PVAQ: pain vigilance and awareness questionnaire; QALYs: Quality Adjusted Life Years; RCT: randomized controlled trial; SCS: spinal cord stimulation; SFMPQ: short form McGill Pain Questionnaire; VAS: visual analog scale

* Based on 33 of 38 patients randomized (87%).
† Adverse events included pain due to the implanted pulse generator in 2 patients and electrode lead migration in 1 patient. Two patients perceived incomplete overlap of the paresthesia with the painful area during trial stimulation, and they had a second electrode lead directly placed. There was
1 infection during trial stimulation, which was successfully resolved and followed by a permanent implantation. Finally, 1 patient turned out to have coagulopathy, which complicated the implantation procedure and prolonged hospitalization.
‡Success defined as ≥50% relief of pain intensity on an NRS for 4 days during daytime or nighttime or a score of ≥6 on a 7-point Likert scale (1 = very much worse and 7 = very much improved) of the PGIC scale for pain and sleep.
§Dural puncture during implantation of lead for test stimulation, followed by subdural hematoma and death (n=1); infection of the SCS system 6 weeks after implantation, slow but incomplete recovery (n=1).

Table 2. Spinal Cord Stimulation Summary Table

Conclusions from CER Executive Summary	New Sources of Evidence	New Findings	Conclusion from SRI
Key Question 1: What is the evidence of efficacy and effectiveness of spinal cord stimulation?			
1. a) Efficacy (Short-term, <5 years): • **Pain, perceived effect of treatment/patient satisfaction:** There is moderate evidence from three small randomized controlled trials that SCS is superior to conventional therapies (CMM, physical therapy or re-operation) in patients with chronic neuropathic pain during the first 2–3 years with respect to patient reported outcomes of pain, and perceived effect of treatment/patient satisfaction. In the only RCT that measured outcomes for a longer period of time, the benefit of SCS decreased over time and was not significantly different than controls for leg pain after 3 years of treatment (see mid-term below). • **Function, quality of life:** The effect on quality of life outcomes is less clear with one RCT reporting substantial benefit of SCS compared with CMM at 6 months follow-up, while another study found quality of life outcomes to be similar between SCS + physical therapy and physical therapy alone at 2 years follow-up. Similarly, function as measured by the Oswestry Disability Index score was better in the SCS group at 6 months versus CMM in one study but the ability to perform daily activities after 3 years was not different in a second study. The strength of this evidence is low. **b) Efficacy (Mid-term, 5-10 years):** • **Pain, quality of life, perceived effect of treatment:** There is low evidence from one small randomized controlled trial that SCS is no different from conventional therapy (physical therapy) in patients with chronic neuropathic pain 5-10 years following implant with respect to pain, quality of life, and patient-reported global perceived effect. **c) Efficacy (Long-term, ≥10 years):** • There are no data available to assess long-term efficacy.	de Vos (2014)[2] Slangen (2014)[3] Schu (2013)[4] De Ridder (2013)[5] Perruchoud (2013)[6]	Two small industry sponsored RCTs compared SCS in patients with diabetic neuropathy to control treatments consisting of conventional or best medical therapy. [2,3] Each reported significant improvement in pain outcomes with SCS compared to controls at 6 months follow-up. No function or quality of life outcomes assessed, and no mid- or long-term follow-up results available. Three small industry sponsored cross-over RCTs compared either HFSCS or burst SCS to placebo stimulation. All had very short follow-up of 1 or 2 weeks. Two studies report significantly improved pain relief with burst SCS vs. placebo in patients with stable benefit from conventional SCS.[4,5] One study reports no difference in pain and quality of life outcomes comparing HFSCS with placebo stimulation.[6]	• New RCTs do not invalidate the previous evidence (criteria A-1 or A3), nor provide major changes in the evidence (criteria B-1 – B4).
Key Question 2: What is the evidence of the safety of spinal cord stimulation?			
1. Revision • There is high evidence from three randomized controlled trials, one prospective comparative cohort study and six case series that revision of SCS components is not uncommon. Overall short-term revision rates ranged from 12–38% of patients. Mid-term revision rates were 42% in one RCT and 60% in	de Vos (2014)[2] Slangen (2014)[3]	• Revision: 2/96 (2%) to include electrode repositioning or replacement • Other: 6/96 (6%) to include infection (n=2), pain from	• New studies do not invalidate the previous evidence (criteria A-2)

Conclusions from CER Executive Summary	New Sources of Evidence	New Findings	Conclusion from SRI
one case series. Reasons for revision include electrode repositioning or replacement, generator revision or replacement, revision of the connecting cable, and total removal and replacement of the system due to infection. There are no long-term data available. **2. Other SCS-related side effects** • Side effects reported varied widely among studies and included infection, change in amplitude by bodily movements, paresthesia in other body parts, pain/irritation from the pulse generator, transient neurological defects, severe wound-related pain at the stimulator implantation site, cerebrospinal fluid leak, and subcutaneous hematoma. The rate of side effects could not be determined from the papers reviewed; however, one RCT reported that all patients experienced at least one side effect. **3. Mortality** • There is high evidence that the rate of mortality due to SCS is low. Among the four comparative studies, 2 deaths were reported in patients receiving SCS (2/139); one as a result of a cardiac event six months following SCS implantation, and the cause of one was not reported. No deaths were recorded in the control groups during the same time period (0/179). Two additional deaths were identified in three case series with five year follow-up; one from a cerebrovascular accident in a patient implanted for cardiac ischemic pain, one as a result of suicide. No death was attributed to SCS; however one patient nearly died as a result of complications that arose following trial stimulation.		pulse generator (n=2), incomplete overlap of paresthesia (n=1), coagulopathy (n=1) • Mortality: 1 (1%) from dural puncture during implantation of lead for test stimulation, followed by subdural hematoma and death	
Key Question 3: What is the evidence that spinal cord stimulation has differential efficacy or safety issues in sub populations?			
1. Age • There is conflicting evidence whether patient age at baseline is associated with outcome. Two studies found that age did not correlate with either pain relief or success (combination of pain relief and patient satisfaction), while one study found that younger age was correlated with pain relief of at least 50%. One of these studies also reported no correlation between age and SF-36 or GPE scores. **2. Sex** • There are mixed results regarding whether patient sex is associated with outcome following SCS. Three studies found that sex was not associated with pain relief, one showed no correlation between sex and SF-36 or GPE scores. In	None	None	• No new data

Conclusions from CER Executive Summary	New Sources of Evidence	New Findings	Conclusion from SRI
contrast, one study found that females had a significantly higher rate of success (pain relief and patient satisfaction), improved function and activity, and decreased medication usage at five years compared with males. **3. Workers' compensation or other disability payments** • One prospective study suggests that whether patients receive workers' compensation/other disability payments or no compensation has no effect on pain relief among patients receiving SCS. Another prospective study found that among patients on workers' compensation, successful outcomes of pain relief, improved function and reduced opioid use was similar between SCS and two control treatment groups. The percentages of success were low in all groups. **4. Duration of pain** • There is moderate evidence from three cohort studies that duration of pain prior to SCS implantation is not associated with pain relief or success within the first year after implantation. **5. Pain intensity** • There is low evidence from one cohort study to suggest that pain intensity at baseline is not associated with success. **6. Time since first lumbar surgery** • There is low evidence from one cohort study to suggest that time since first lumbar surgery is not predictive of success. **7. Number of prior surgeries for pain** • There is moderate evidence from two cohort studies to suggest that the number of prior of operations for pain is not associated with pain relief (or success). One study additionally found no correlation between prior operations for pain and function/activity/medication usage at five years. **8. Pain location** • There is low evidence from four cohort studies that pain location does not affect outcomes. **9. Laterality of pain** • There is low evidence from one cohort study on FBSS patients with open workers' compensation claims that patients with unilateral pain have better pain relief and functional outcomes (as measured by the RDQ) at 12 months compared with patients with bilateral pain. **10. Allodynia or hypoesthesia at baseline** • There is low evidence from one cohort study that the presence of allodynia at			

Conclusions from CER Executive Summary	New Sources of Evidence	New Findings	Conclusion from SRI
baseline negatively correlates with success at one year, while the presence of hypoesthesia at baseline was not predictive of success. **11. McGill Pain Questionnaire** • There is conflicting evidence from two studies that the McGill Pain Questionnaire is associated with pain relief or success at follow-up with conflicting results. One study found an association between the evaluative subscale while the other study found no association with any subscale and outcome. **12. Minnesota Multiphasic Personality Inventory (MMPI)** • There is conflicting evidence from two studies that the MMPI is associated with pain relief or success at follow-up with conflicting results. One study found an association between the depression subscale while the other study found no association with any subscale and outcome. **13. SF-36 Mental Health scores** • There is low evidence from one cohort study on FBSS patients with open workers' compensation claims that patients with baseline SF-36 Mental Health scores in the top third have better pain relief and functional outcomes (as measured by the RDQ) at 12 months than do those patients who scored in the bottom third at baseline.			
Key Question 4: What is the evidence of cost implications and cost-effectiveness of spinal cord stimulation?			
Cost Effectiveness • There is moderate evidence from three complete economic evaluations that in the short-term, SCS is associated with improved outcomes and increased costs compared with CMM and/or re-operation for the treatment of neuropathic pain. In the long-term, SCS appears to be dominant over the control treatments; however, only one study included in this assessment was conducted in a U.S. setting. More specifically, we found that there is some evidence that SCS is cost-effective at moderate (<$20,000) incremental cost effectiveness ratio (ICER) levels compared with CMM or re-operation, and that SCS cost-effectiveness increases and may be dominant over time compared with control treatments (i.e., CMM or re-operation) assuming device longevity of 4 years and at least a 30% pain threshold criteria. However, the assumption of continued efficacy past 3 years is questionable from the only RCT reporting pain 5-10 years after implantation. Furthermore, only one study was conducted in a US setting.	Zucco (2015)[7]	• Zucco et al. used a before-after study design to evaluate the cost-effectiveness and cost utility of SCS compared to conventional care in patients with FBSS. They report an ICUR: €47,000/QALY and ICER: €3,222/NRS. They conclude that if decision makers' willingness to pay per QALYs was €60,000, SCS implantation would be cost-effective in 80% and 85% of cases, according to the NHS's and societal point of views, respectively.	• New cost-utility study does not invalidate the previous evidence (criteria A-1 or A-3), nor provide major changes in the evidence (criteria B-1).

References

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3. Slangen R, Schaper NC, Faber CG, et al. Spinal cord stimulation and pain relief in painful diabetic peripheral neuropathy: a prospective two-center randomized controlled trial. *Diabetes Care* 2014; **37**(11): 3016-24.

4. Schu S, Slotty PJ, Bara G, von Knop M, Edgar D, Vesper J. A prospective, randomised, double-blind, placebo-controlled study to examine the effectiveness of burst spinal cord stimulation patterns for the treatment of failed back surgery syndrome. *Neuromodulation* 2014; **17**(5): 443-50.

5. De Ridder D, Plazier M, Kamerling N, Menovsky T, Vanneste S. Burst spinal cord stimulation for limb and back pain. *World Neurosurg* 2013; **80**(5): 642-9 e1.

6. Perruchoud C, Eldabe S, Batterham AM, et al. Analgesic efficacy of high-frequency spinal cord stimulation: a randomized double-blind placebo-controlled study. *Neuromodulation* 2013; **16**(4): 363-9; discussion 9.

7. Zucco F, Ciampichini R, Lavano A, et al. Cost-Effectiveness and Cost-Utility Analysis of Spinal Cord Stimulation in Patients With Failed Back Surgery Syndrome: Results From the PRECISE Study. *Neuromodulation* 2015; **18**(4): 266-76; discussion 76.

Appendix A. Search Strategy and Electronic Databases

The detailed strategy below is presented in Medline and EMBASE syntax.

Search Strategy
(Aug 1, 2013 to Aug 25, 2016)
Limited to English language, human population

Database: MEDLINE

1.	"Spinal cord stimulation" OR "Spinal cord stimulation"[MeSH] OR "spinal cord stimulator" OR "spinal cord stimulators"
2.	#1 NOT "Case Reports"[Publication Type]

Database: EMBASE

'spinal cord stimulation'/exp OR 'spinal cord stimulator'/exp AND [humans]/lim AND [English]/lim AND [abstracts]/lim AND [5-1-2013]/sd NOT [12-1-2013]/sd AND [2010-2014]/py

Parallel strategies were used to search the Cochrane Library and others listed below. Keyword searches were conducted in the other listed resources.

Electronic Database Searches
The following databases have been searched for relevant information:
Cochrane Database of Systematic Reviews
Cochrane Registry of Clinical Trials
EMBASE
PubMed

Appendix B. List of excluded articles after full-text review

Study	Reason for Exclusion:
Systematic reviews	
Bicket MC, Dunn RY, Ahmed SU. High-Frequency Spinal Cord Stimulation for Chronic Pain: Pre-Clinical Overview and Systematic Review of Controlled Trials. Pain Med 2016.	No quantitative synthesis
Cruccu G, Garcia-Larrea L, Hansson P, et al. EAN guidelines on central neurostimulation therapy in chronic pain conditions. Eur J Neurol 2016.	No new RCTs included since previous report
Grider JS, Manchikanti L, Carayannopoulos A, et al. Effectiveness of Spinal Cord Stimulation in Chronic Spinal Pain: A Systematic Review. Pain Physician 2016; 19(1): E33-54.	No quantitative synthesis
Hou S, Kemp K, Grabois M. A Systematic Evaluation of Burst Spinal Cord Stimulation for Chronic Back and Limb Pain. Neuromodulation 2016; 19(4): 398-405.	No quantitative synthesis
Pope JE, Falowski S, Deer TR. Advanced waveforms and frequency with spinal cord stimulation: burst and high-frequency energy delivery. Expert Rev Med Devices 2015; 12(4): 431-7.	No quantitative synthesis
Russo M, Van Buyten JP. 10-kHz High-Frequency SCS Therapy: A Clinical Summary. Pain Med 2015; 16(5): 934-42.	No new RCTs included since previous report
Shamji MF, Westwick HJ, Heary RF. Complications related to the use of spinal cord stimulation for managing persistent postoperative neuropathic pain after lumbar spinal surgery. Neurosurg Focus 2015; 39(4): E15.	Narrative review
Verrills P, Sinclair C, Barnard A. A review of spinal cord stimulation systems for chronic pain. J Pain Res 2016; 9: 481-92.	No new RCTs included since previous report
RCTS	
Hayek SM, Veizi E, Hanes M. Treatment-Limiting Complications of Percutaneous Spinal Cord Stimulator Implants: A Review of Eight Years of Experience From an Academic Center Database. Neuromodulation 2015; 18(7): 603-8; discussion 8-9.	Retrospective study of an administrative database
Kapural L, Yu C, Doust MW, et al. Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: The SENZA-RCT Randomized Controlled Trial. Anesthesiology 2015; 123(4): 851-60.	HFSCS vs. LFSCS, no non-SCS controls
Rigoard P, Desai MJ, North RB, et al. Spinal cord stimulation for predominant low back pain in failed back surgery syndrome: study protocol for an international multicenter randomized controlled trial (PROMISE study). Trials 2013; 14: 376.	Study protocol
Roulaud M, Durand-Zaleski I, Ingrand P, et al. Multicolumn spinal cord stimulation for significant low back pain in failed back surgery syndrome: design of a national, multicentre, randomized, controlled health economics trial (ESTIMET Study). Neurochirurgie 2015; 61 Suppl 1: S109-16.	Multicolumn vs. monocolumn stimulation. Awaiting publication of results.
Van Havenbergh T, Vancamp T, Van Looy P, Vanneste S, De Ridder D. Spinal cord stimulation for the treatment of chronic back pain patients: 500-Hz vs. 1000-Hz burst stimulation. Neuromodulation 2015; 18(1): 9-12; discussion	Comparing two modes of SCS, no non-SCS controls

Appendix C. Current comparative studies in ClinTrials.gov assessing SCS (accessed Aug 22, 2016)

NCT Number	Title	Conditions	Interventions	Control	Enrollment	Funded By	Start Date	Completion Date
NCT02514590	Wireless High Frequency Spinal Cord Stimulation for Chronic Pain	Back Pain	HFSCS	Conventional SCS	80	Industry	Mar-16	null
NCT01609972	Comparison of Senza to Commercial Spinal Cord Stimulation for the Treatment of Chronic Pain	Chronic LBP	HFSCS	Conventional SCS	356	Industry	Jun-12	Jun-15
NCT01923285	A Safety and Effectiveness Trial of Spinal Cord Stimulation of the Dorsal Root Ganglion for Chronic Lower Limb Pain	Chronic LBP	Dorsal root ganglion stimulation (AXIUM)	Conventional SCS	152	Industry	Aug-13	Dec-18
NCT01624740	High Rate Spinal Cord Stimulation (SCS) for Chronic Pain	Chronic Pain	High Rate Stimulation	Low Rate Stimulation	20	Industry	Jun-12	Dec-13
NCT02250469	A Randomised Pilot Study to Assess Differences in Stimulation Induced Paresthesia Between 2 Spinal Cord Stimulation Systems	Chronic Pain	Dorsal root ganglion stimulation (AXIUM)	Conventional SCS	34	Industry	Sep-14	May-17
NCT02093793	Safety and Effectiveness Study of the Precision SCS System Adapted for High-Rate Spinal Cord Stimulation	Chronic Pain, Back Pain	PRECISION SCS Adapted for High-Rate SCS	Conventional SCS	406	Industry	Mar-14	Oct-16
NCT02265848	High Frequency Stimulation Trials in Patients With Precision Spinal Cord Stimulator System	Chronic Pain, LBP, Radiculopathy, CRPS	HFSCS	Conventional SCS	22	Other	Oct-14	Jan-15
NCT01162993	Effect of Spinal Cord Stimulation (SCS) in Painful Diabetic Polyneuropathy	Diabetic Neuropathies, Pain,	Conventional SCS	Treatment as usual	40	Other	Apr-10	Jan-18
NCT01628237	Effectiveness and Cost Management of Multicolumn Spinal Cord Stimulation in Neuropathic Pain Patients With Failed Back Surgery Syndrome	FBSS	Multicolumn SCS	Monocolumn SCS	115	Other	May-12	Jan-15
NCT01697358	Spinal Cord Stimulation for Predominant Low Back Pain	FBSS, Back Pain, Leg pain	Conventional SCS	OMM	300	Industry	Jan-13	Apr-16
NCT02112474	The Pain Suppressive Effect of Alternative Spinal Cord Stimulation Frequencies	FBSS, Neuropathic Pain	High frequency SCS	Low frequency SCS	30	Other	Nov-14	Nov-16
NCT01486108	Burst Spinal Cord Stimulation for Neuropathic Pain	Neuropathic Pain	Burst SCS	Placebo, Tonic SCS	15	Other	Jan-11	Sep-11

CRPS: Complex Regional Pain Syndrome; FBSS: failed back surgery syndrome; HFSCS: high frequency spinal cord stimulation; LBP: low back pain; SCS: spinal cord stimulation;

Washington State Health Care Authority

Vertebroplasty, Kyphoplasty, Sacroplasty

Assessing signals for update

December 9, 2016

Health Technology Assessment Program (HTA)
Washington State Health Care Authority
PO Box 42712
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Vertebroplasty, Kyphoplasty, Sacroplasty: Assessing Signals for Update

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December 9, 2016

Contents

1. Introduction

A Health Technology Assessment titled: ***Vertebroplasty, Kyphoplasty, Sacroplasty***, was published on November 5, 2010 by the Health Care Authority. Findings and Coverage Decision was adopted on March 18, 2011. The Committee's Coverage Decision is summarized below.

HTCC Coverage Determination

Vertebroplasty, Kyphoplasty and Sacroplasty are not covered benefits.

HTCC Reimbursement Determination

Vertebroplasty, Kyphoplasty and Sacroplasty are not covered benefits.

Committee Findings

Having considered the evidence based technology assessment report and the written and oral comments, the committee identified the following key factors and health outcomes, and evidence related to those health outcomes and key factors:

1. Evidence availability and technology features

The committee concludes that the best available evidence on Vertebroplasty, Kyphoplasty and Sacroplasty has been collected and summarized. Summary of committee considerations follows.

- The evidence based technology assessment report indicates that vertebral compression fractures and sacral insufficiency fractures occur, commonly as part of the natural disease progression of osteoporosis or osteopenia. Some patients with fractures are asymptomatic but others experience acute pain, loss of function, and decreased quality of life thought to be caused by the fracture.
- Vertebroplasty (PV), kyphoplasty (KP) and sacroplasty are all cementoplasty techniques that aim to relieve pain thought to be caused by the fracture by stabilizing the fractured bone(s). Vertebroplasty and sacroplasty are considered minimally invasive procedures and are usually performed using only local anesthesia or with conscious sedation. General anesthesia may be used. Kyphoplasty almost always requires general anesthesia and at least one overnight stay in the hospital. The patient must lie prone during all three procedures. Multiple levels can be treated during the same session. Patients are usually selected based on failure of conservative

treatment or incapacitating pain. Alternatives include conservative management and surgical fixation, though invasive surgery may be problematic due to common comorbidities in the elderly and female population most often considered for this treatment.

- Despite increasing use of these procedures (rates of kyphoplasty doubled between 2001 and 205), the evidence for the procedure remains low and the efficacy, safety and economic impact are not well understood. Patients are generally elderly women with osteopenic fractures and most included studies focused on this population.
- with conservative care which resolves pain in 4 to 6 weeks and is generally recommended first. However, patients with acute fractures (less than six weeks) may be more likely to experience pain relief and the rapid recovery from debilitating pain is a primary treatment aim. Fracture age is difficult to determine as patients may have difficulty pinpointing the onset of pain and whether a certain event may be associated with the onset.
- In addition to typical complications from invasive procedures, cementoplasty techniques include risk of possible increase of subsequent compression fractures near a cemented vertebra due to increased rigidity of the treated vertebrae and risk of cement leakage.
- Evidence included in the technology assessment review was obtained through systematic searches of the medical literature for systematic reviews including meta-analyses, randomized controlled trials, observational studies, and economic studies. 11 RCTs, 23 Observational studies, and 3 economic studies met inclusion criteria and were included in the review. Overall strength of evidence from these studies was low to very low or inconclusive. Two RCTs compared vertebroplasty with sham procedure; three RCTs compared vertebroplasty to conservative care; one RCT compared kyphoplasty to conservative care; and one RCT compared kyphoplasty and vertebroplasty.
    - The evidence based technology assessment report identified 4 clinical guidelines; there is no National Coverage decision on vertebroplasty, kyphoplasty or sacroplasty.
    - The committee also reviewed information provided by the state agencies, and public members; and heard comments from the evidence reviewer, clinical expert, HTA program, agency medical directors and the public.

2. Is it safe?

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is safe. Key factors to the committee's conclusion include:

- The evidence based technology assessment report concluded that the overall strength of evidence for safety is low for vertebroplasty and kyphoplasty and very low for sacroplasty and evidence based estimate of effect are uncertain. While it appears that rates of serious complications are low for vertebroplasty and kyphoplasty, studies with long-term (> 5 year) follow-up are few and comparative studies, especially RCTs, may have too few patients to detect more rare but serious outcomes. Primary safety outcomes reported include rates of new fracture, cement leakage, pulmonary cement embolism, and mortality related to vertebroplasty and kyphoplasty.

- *New fractures (adjacent or non-adjacent)* – in comparative studies, rates of new fractures were up to 30% at 12 months, with no consistent pattern across studies of increased fracture rates for any one treatment (vertebroplasty, kyphoplasty, or conservative treatment). One RCT reported that the distribution of fracture location (adjacent or non-adjacent) was similar for vertebroplasty and non-surgical patients. Systematic reviews, incorporating information on longer-term follow-up with a large (pooled) number of patients in case series, suggest that rates of new fracture may be slightly higher in vertebroplasty (18-19% of patients, 16-21% of vertebral levels) than kyphoplasty (7-17% of patients, 11-13% of levels). One systematic review concluded that the proportion of new fractures that were in adjacent vertebrae was higher for kyphoplasty (75%) than for vertebroplasty (52%).
- *Cement leakage* – in comparative studies, rates of cement leakage (largely asymptomatic) approached 80% for vertebroplasty and 50% for kyphoplasty, with some evidence that leakage is more common with vertebroplasty than with kyphoplasty. Systematic reviews also suggest that leakage is more common in vertebroplasty (19.7% - 79.0% of levels treated) than in kyphoplasty (0.51% - 11.2%), and that rates of symptomatic leakage are quite low (0.5%-1.6%of levels treated for vertebroplasty and 0% - 0.3% for kyphoplasty).
- *Pulmonary cement embolism* – as a result of differential surveillance in RCTs, nonrandomized studies, and case series, rates vary widely across studies. One RCT using computed tomography to detect emboli reported that 26% (15/54) of vertebroplasty patients had a cement embolism, all of which were asymptomatic. No incidents of symptomatic embolism were reported in comparative studies. A systematic review of cement embolism reported rates of 1.6% for asymptomatic PCE and 1.1% for symptomatic PCE (all but one of the case series included in the review were of vertebroplasty patients).
- *Mortality* – systematic reviews (based on case series) estimate mortality rates at 2.1% for vertebroplasty and 2.3%-3.2% for kyphoplasty; the timing of mortality was not reported. Perioperative mortality rate for kyphoplasty was .01% across 11 case series. Since the majority of patients receiving these procedures are elderly and/or have malignant disease, the extent to which mortality can be attributed to the procedures is unclear.
- *Sacroplasty* – the evidence based technology assessment report indicates that the overall strength of evidence about safety of sacroplasty is very low, and all data are from case series. Cement leakage was the only reported complication and occurred in 7 of 34 (20.6%) patients across four case series.

3. Is it effective?

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is effective. Key factors to the committee's conclusion include:

- Vertebroplasty
    - *Pain Relief* – the evidence based technology assessment report concluded that the overall strength of evidence about effectiveness of vertebroplasty to reduce/relieve pain is *low*; any effect estimate is uncertain and may change with additional research. The low strength of evidence and lack of ability to estimate effect based on evidence is due to the limitations of the studies and that the studies reported differing outcomes (some studies showed benefit others did not). The RCTs were limited to patients with osteoporotic fractures and evaluated short-term effects (≤12 months). Two sham-controlled RCTs demonstrated no difference in pain relief (up to 1month in one study and 6 months in the other), though both studies were limited in power to detect differences in the proportion of patients with clinically meaningful improvement. Another RCT demonstrated statistically significant improvement in pain scores sustained to the 12-month follow-up compared to conservative care and included more patients but was not blinded and did not include a placebo comparison. Two small RCTs reported no advantage for vertebroplasty over 2 weeks or 12 months. Four nonrandomized studies with follow-up up to one year found that vertebroplasty was more effective in reducing pain than conservative medical treatment at up to approximately six months, but no difference at one year.
    - *Function and quality of life* – the evidence based technology assessment report concluded that the overall strength of evidence about effectiveness of vertebroplasty to improve patient function or quality of life is *low*; any effect estimate is uncertain and may change with additional research. One larger RCT demonstrated that PV was more effective than conservative treatment in improving functioning as measured by the QualEffo and RDQ, although it is possible that early differences in improvement diminish over time. Two small RCTs found comparable improvements in function over 2 weeks and 12 months for vertebroplasty and non-surgical patients. In 4 non-randomized studies, vertebroplasty showed superior effectiveness in improvements in functioning and quality of life in the first 3-6 months was followed by equivalence at one year.
- Kyphoplasty
    - *Pain Relief* – the evidence based technology assessment report concluded that the overall strength of evidence about effectiveness of kyphoplasty to relieve/reduce pain is very low; any effect estimate is uncertain and may change with additional research.
    - Only one RCT compared kyphoplasty with conservative treatment, reporting that while pain was reduced more rapidly in kyphoplasty patients, this advantage over conservative treatment was diminished by the one-year follow-up. Because of the paucity of RCTs comparing kyphoplasty to conservative treatment, the overall strength of evidence is low and effect estimates may change with additional research. In two non-randomized studies, kyphoplasty reduced pain more than conservative medical treatment for periods up to 3 years.
    - *Function and quality of life* – the evidence based technology assessment report indicated that it is uncertain whether kyphoplasty improves patient functioning and quality of life. In these two studies, kyphoplasty improved a limited set of functional outcomes more than conservative medical treatment.
- Sacroplasty

- There is no evidence of efficacy for sacroplasty. Very limited data from 9 case series (N = 141 total patients) is available, the case series showed pain relief with sacroplasty; but the absence of comparative studies, small patient size do not permit an evidence based conclusion.

4. Is it cost-effective?

The committee discussed multiple key factors that were important for consideration in their overall decision on whether the technology has value and is cost-effective. Summary of committee considerations follows:

- The evidence based technology report summarized three economic studies, however, because the evidence about efficacy, effectiveness, and safety is low to very low and evidence based estimates of effect are uncertain; conclusions about cost effectiveness are premature. No cost studies were conducted with U.S. data, the cost effectiveness of vertebroplasty, kyphoplasty or sacroplasty in a US setting is unknown.
- The economic impact of complications, reoperation, or revision following vertebroplasty, kyphoplasty, or sacroplasty is unknown.
- Washington state agency utilization and cost information indicates that the single agency that reimburses (UMP) for these procedures expended $868,543 in the last four years, with an average cost of $10,837; and both procedure volume and costs are rising annually.

5. Medicare Decision and Expert Treatment Guidelines

The committee deliberations included a discussion of National Medicare Decisions and expert treatment guidelines, and an understanding that the committee must find substantial evidence to support a decision that is contrary. RCW 70.14.110.

The Committee reviewed and discussed the expert guidelines as identified and reported in the technology assessment report. Overall, the clinical guidelines and Medicare coverage decisions included in the evidence report and the AAOS guideline published subsequent either do not cite evidence or rely on evidence assess as low or very low quality or consensus statements.

- Centers for Medicare and Medicaid Services (CMS) have no published National or Local coverage determinations for vertebroplasty, kyphoplasty or sacroplasty.
- The evidence based technology assessment report identified three guidelines on vertebroplasty, kyphoplasty and/or sacroplasty, although no guideline specifically addressed the procedures for osteoporosis or malignancy – the studied indications.
    - Two guidelines mentioned vertebroplasty and kyphoplasty as part of the assessment and management of spinal cord compression and chronic pain and indicate they may be considered.
        - Institute for Clinical Systems Improvement (ICSI), 2008

    - National Collaborating Centre for Cancer, National Institute for Health and Clinical Excellence (NICE), 2008

- American Society of Interventional and Therapeutic Neuroradiology, Society of Interventional Radiology, American Association of Neurological Surgeons/Congress of Neurological Surgeons, and American Society of Spine Radiology -- A consensus statement on percutaneous vertebral augmentation was developed: "It is the position of the Societies that vertebral augmentation with vertebroplasty or kyphoplasty is a medically appropriate therapy for the treatment of painful vertebral compression fractures refractory to medical therapy when performed for the medical indications outlined in the published standards1-3."
- American Association of Orthopaedic Surgeons (AAOS) -- recommend against vertebroplasty for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact. *Strength of Recommendation: Strong*. Kyphoplasty is an option for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact. *Strength of Recommendation: Weak.*

2. Purpose of Report

The purpose of this literature update is to determine whether or not there is sufficient evidence published after the original report to conduct a re-review of this technology based on the presence of preset signal criteria. The key questions included the following:

Key question 1
What is the evidence of efficacy and effectiveness of vertebroplasty, kyphoplasty or sacroplasty? Including consideration of:

a. Short-term and long-term outcomes
b. Impact on function, pain, quality of life
c. Other reported measures including: use of pain medications and opioids, return to work

Key Question 2
What is the evidence of the safety of vertebroplasty, kyphoplasty or sacroplasty? Including consideration of:

a. Adverse events type and frequency (mortality, major morbidity, other)
b. Revision/re-operation rates (if not addressed in efficacy)

Key Question 3
What is the evidence that vertebroplasty, kyphoplasty or sacroplasty has differential efficacy or safety issues in sub populations? Including consideration of:

- Gender
- Age
- Psychological or psychosocial co-morbidities
- Diagnosis or time elapsed from fracture
- Other patient characteristics or evidence based patient selection criteria
- Provider type, setting or other provider characteristics
- Payer/beneficiary type: including worker's compensation, Medicaid, state employees

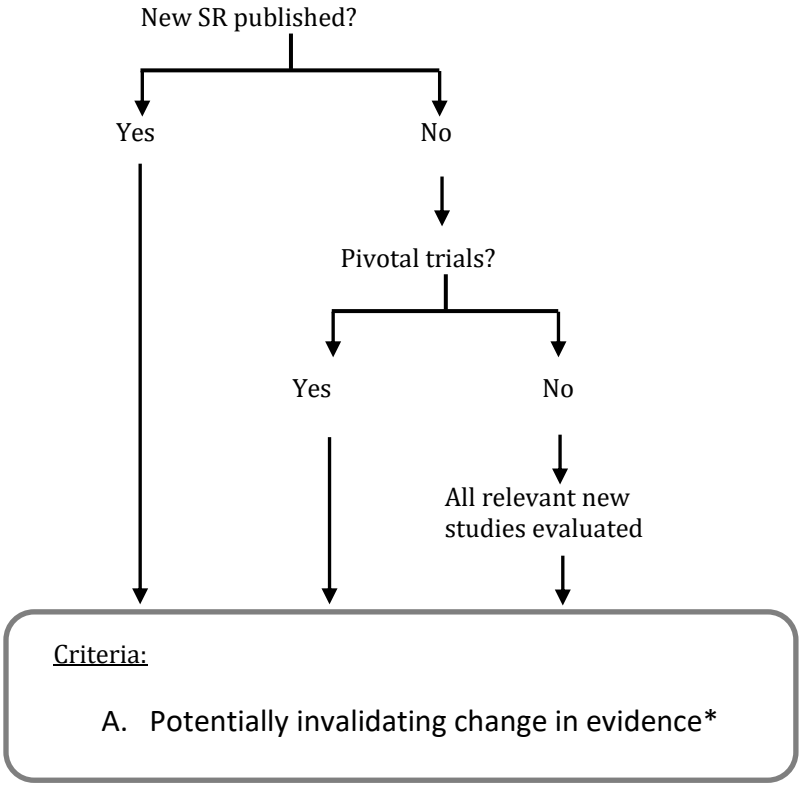
Key Question 4
What is the evidence of cost implications and cost-effectiveness of vertebroplasty, kyphoplasty and sacroplasty? Including consideration of:

a. Costs (direct and indirect) in the short term and over expected duration of use
b. Revision/re-operation (if not addressed in efficacy)

3. Methods

To determine the need for systematic review update, the following algorithm was followed.

Figure 1. Algorithm of the modified Ottawa Method of Identifying Signals for SR



*A-1. Opposing findings: Pivotal trial or SR including at least one new trial that characterized the treatment in terms opposite to those used earlier

A-2. Substantial harm: Pivotal trial or SR whose results called into question the use of the treatment based on evidence of harm or that did not proscribe use entirely but did potentially affect clinical decision making

A-3. Superior new treatment: Pivotal trial or SR whose results identified another treatment as significantly superior to the one evaluated in the original review, based on efficacy or harm.

†B-1. Important changes in effectiveness short of "opposing findings"

B-2. Clinically important expansion of treatment

B-3. Clinically important caveat

B-4. Opposing findings from discordant meta-analysis or nonpivotal trial

Updates

3.1 Literature Searches

We conducted a limited electronic literature of Medline for systematic reviews with meta-analysis during the period March 1, 2010 through November 26, 2016 using search terms used for the original report. Appendix A includes the search methodology for this topic. In addition, we searched the FDA website to determine if there was approval of new devices or indications for vertebroplasty, kyphoplasty or sacroplasty and for individual cost-effectiveness studies for KQ 4.

3.2 Study selection

We sought systematic reviews of randomized controlled trials (RCTs) of efficacy and safety with meta-analysis that included articles that met inclusion and exclusion criteria similar to the original report. In addition we sought systematic reviews reflecting updates or new advances for the technology. Secondary to the large number of citations returned, we focused on screening only systematic reviews and meta-analyses of RCTS published between 2011 and 2016. Although quality of systematic reviews was not formally evaluated for this report, we chose three systematic reviews that were the most comprehensive and of high quality based on the following: report of search strategies (two or more data bases and description of dates searched), number of included relevant RCTs, pre-stated inclusion and exclusion criteria, information on methodologies used for synthesis of data, inclusion of patient reported or safety outcomes and evaluation of the strength of the body of literature using GRADE or another analogous system. Only systematic reviews of RCTs were included. A summary of the three SRs is found in Appendix B.

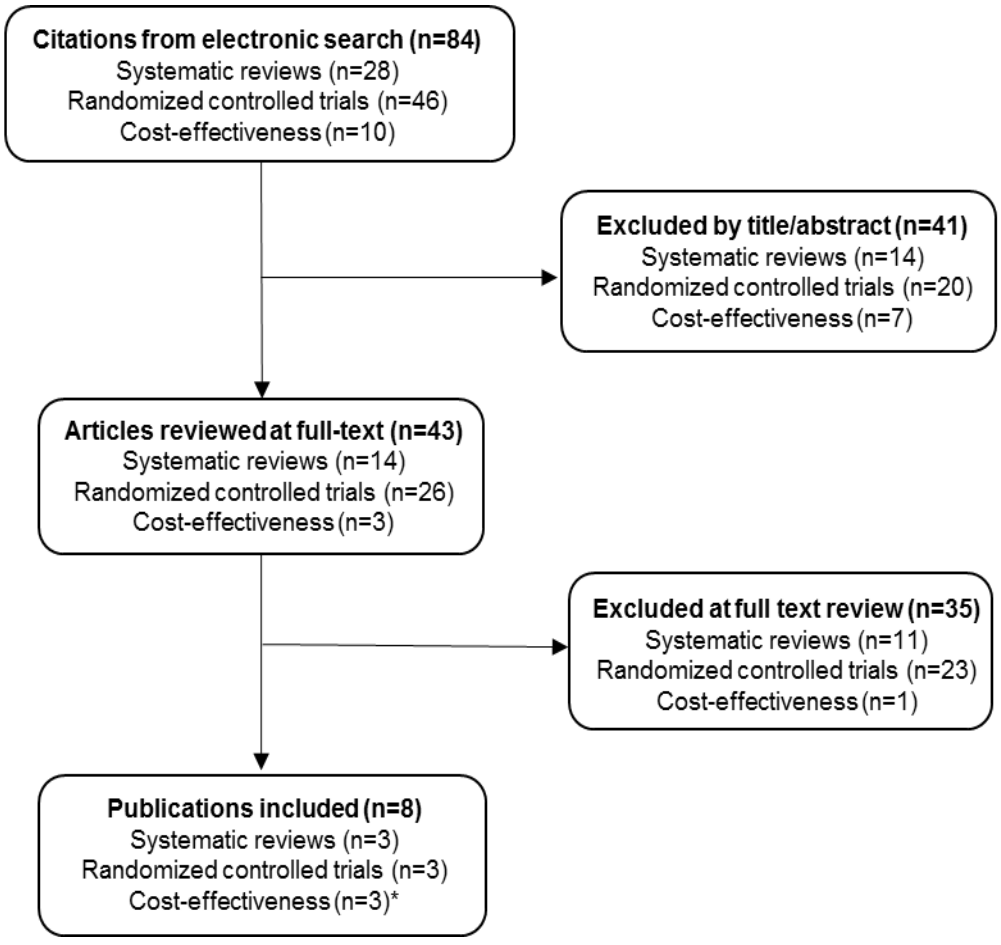
4. Results

4.1 Search

We identified 28 systematic reviews from the electronic search that addressed in part or in full key questions 1 and 2, Figure 2. We reviewed the full text of 14 systematic reviews that most closely met the inclusion criteria (see excluded studies and the reasons for exclusion in Appendix C). Two included systematic reviews provided analysis of differential efficacy (Key Question 3) and an additional three RCTs were identified that provided information on subpopulations not included in the systematic reviews. One of the new RCTs also provided data for key question 1. We found three new cost-effectiveness analyses (Key Question 4) one of which evaluated a subset of data from a study included in the previous HTA, two others were conducted as part of a systematic review.

A table of new FDA approved devices is found in Appendix D. All were considered to be variations of existing devices versus new devices and were approved via the 510K process. In May 2015, Stryker received 510K approval to expand the indications for use of VertaPlex HV Radiopaque Bone Cement to pathological fractures of the sacral vertebral body. The FDA warning issued for bone cement has not changed since the previous report.
(http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062126.htm)

Figure 2. Electronic search results for systematic reviews



*One of the included systematic reviews also conducted a formal economic evaluation and so is included in the final count for both systematic reviews and cost-effectiveness studies. The systematic review for the other economic study did not meet inclusion criteria.

4.2 Identifying signals for re-review

Table 1 shows the original key questions, the conclusions of the original report, the new sources of evidence, the new findings, and the recommendations of Spectrum Research, Inc. (SRI) regarding the need for update.

Table 1. Vertebroplasty, Kyphoplasty, Sacroplasty Summary Table for Key Question 1.

Key Question 1. What is the evidence of efficacy and effectiveness of vertebroplasty, kyphoplasty, and sacroplasty?			
Conclusions from CER Executive Summary	**New Sources of Evidence**	**New Findings**	**Conclusion from SRI**
Vertebroplasty (PV) vs. sham surgery ○ There is low evidence from two RCTs, PV was no more effective than sham surgery in reducing pain or improving function or quality of life at one month and three months. Pain improved in both groups by 2.6-3.0 points at follow-up, RDQ scores improved by 3.7-5.3, and EQ-5D improved by 0.1-0.2 points.	**Efficacy** *Systematic Review*: Buchbinder (2015, Cochrane Review)[3] (Updates to the two previously included RCTs; no new RCTs) *New RCT:* Clark (2016)[4] (not included in Buchbinder 2015) **Effectiveness** Not explored	**Efficacy**: • No between-group differences in outcome were observed for pain, RDMQ, QUALEFFO, EQ-5D at any time point in patients with osteoporotic fractures based on pooled analysis in the Buchbinder Cochrane review up *to 24 months*. • Clark RCT: PV was associated with reduction in pain and disability (RMDQ) at all time frames to 6 months; QUALEFFO scores were higher for PV at 0.5 and 6 months. • Preliminary pooled effect estimates combining Clark RCT data with data from the Buchbinder Cochran review (See Appendix C) suggests that: ○ Success, defined as with improvement in	• Short term (≤ 6months): Preliminary pooled analysis which includes the new RCT suggests an important change in the evidence for pain improvement success from no difference to difference favoring PV. (Criterion B1). • Short term: Pooled estimates for function do not provide a major change in the

Key Question 1. What is the evidence of efficacy and effectiveness of vertebroplasty, kyphoplasty, and sacroplasty?			
Conclusions from CER Executive Summary	**New Sources of Evidence**	**New Findings**	**Conclusion from SRI**
		pain of 2.5 units (Buckbinder), or >30% or more from baseline (Kallmes) or pain less than 4 out of 10 (Clark) was more common following PV. Pooled RRs (95% CI) at 1 month were 1.6 (1.0, 2.5), at 3 months 1.6 (1.1, 2.3) and at 6 months 1.4 (1.1, 1.9) ○ While there was statistically significant improvement in pain scores (VAS or NRS) at 1month (pooled MD -0.94,95% CI -1.59, -0.29) and 3 months (pooled MD -1.04, 95% CI 1.98, -0.09) it is likely not clinically meaningful; pooled mean difference in pain scores was similar between PV and sham at 1-2 weeks and at 6 months. ○ Reduction in disability (RMDQ) was similar between groups at 1-2 weeks, 3 and 6 months; a pooled MD of -1.72 (95%CI -3.13, -0.31) at 1 month was statistically significant but may not be clinically meaningful.	evidence (Criteria B1-4) • Longer term (>6 months to 24 months) Updated analyses from the systematic review do not change the conclusions of the previous report (criteria A-1 or A3) nor provide major changes in the evidence (Criteria B1-4)

Key Question 1. What is the evidence of efficacy and effectiveness of vertebroplasty, kyphoplasty, and sacroplasty?			
Conclusions from CER Executive Summary	**New Sources of Evidence**	**New Findings**	**Conclusion from SRI**
		○ Pooled mean differences in EQ5D reached statistical significance at 1 and 6 months favoring PV., but mean differences were small, ranging from 0.01 to 0.06 across time frames.	
<u>Vertebroplasty (PV) vs. conservative treatment (CMT)</u> **Efficacy:** There is low evidence: • In a large RCT comparing PV with conservative treatment, PV was more effective than conservative treatment in reducing self-reported pain intensity for follow-up points of up to one year, with improvements of 6.6 points and 3.7 points respectively. • In this large RCT, improvement in RDQ scores was greater for PV patients than for CMT patients by 2-3 points over a year. PV patients also improved more than CMT patients on the QualEffo, but scores for the two groups	**Efficacy** *Systematic Reviews*: Buchbinder (2015, Cochrane)[3] (3 new RCTs in addition to the 1 RCT included in previous report) Li (2015)[6] (2 of the 3 new RCTs included) 1 New RCT: Yang (2016)[8]; (patients >70 years old) **Effectiveness:** Not explored	**Efficacy:** • Buchbinder: VP was superior to CMT in pain and disability (RMDQ) improvement over 2 wks. to 12 mos. follow-up (for pain only, no difference at 24 mos. in 1 RCT) and for EQ-5D from 2 weeks to 3 mos. follow-up (but no difference at 6 and 12 mos.). There was no difference between groups for QUALEFFO at any time point. Statistical heterogeneity varied from unimportant to considerable • Li: Evaluated pain only. Greater pain relief with PV than CMT at all time-points but only mid- and long-term were significant (p=0.003 and 0.000, respectively, vs. p=0.06 in the early-term) • Yang RCT: Early PV yielded faster, better pain relief	• Findings from systematic reviews including new RCTs do not change the conclusions from the previous report (criteria A-1 or A3), nor provide major changes in the evidence (criteria B1-B4).

Key Question 1. What is the evidence of efficacy and effectiveness of vertebroplasty, kyphoplasty, and sacroplasty?			
Conclusions from CER Executive Summary	**New Sources of Evidence**	**New Findings**	**Conclusion from SRI**
were similar at 12 months. • In two small RCTs, PV and CMT patients showed comparable improvement in pain, with inconsistent findings for functional outcomes **Effectiveness:** There is low evidence • In four cohort studies (2 prospective, 2 retrospective): ○ PV was more effective than CMT in reducing pain (from 7.5-9 to 0.7-3.5) up to 6 months, but pain levels were comparable for the two groups after one year. ○ For a very limited set of functional outcomes, PV led to earlier improvements than CMT, followed by equivalent levels of functioning after 6 months to a year.		and improved functional outcomes compared with conservative treatment, which were maintained for 1 year. Findings consistent with previous report.	
<u>Kyphoplasty (KP) vs. conservative treatment (CMT)</u> **Efficacy:**	**Efficacy:** *Systematic Reviews*:	**Efficacy:** • The Li systematic review evaluated pain only. KP	• Analyses from the systematic reviews

Key Question 1. What is the evidence of efficacy and effectiveness of vertebroplasty, kyphoplasty, and sacroplasty?			
Conclusions from CER Executive Summary	**New Sources of Evidence**	**New Findings**	**Conclusion from SRI**
• There is low evidence from one RCT • KP was more effective than CMT by 0.9-2.2 points in reducing pain intensity for follow-up points up to one year. • Pain was reduced more rapidly in KP patients, and group differences were diminished by 12 months. • KP was more effective than CMT in improving functional outcomes (EQ-5D, RDQ, SF-36) over one year, but group differences were diminished at 12 months. **Effectiveness:** There is very low evidence from two cohort studies (1 prospective and 1 retrospective): • KP reduced pain more than CMT for periods up to 3 years. • KP improved a limited set of functional outcomes more than CMT	Li (2015)[6] (3 Updates to previously included RCT) Stevenson (2014)[7] (2 updates to previously included RCT) **Effectiveness:** Not explored	provided greater pain relief than CMT at all time-points but only early (1 week) and mid-term (2-3 months) were significant (p=0.000 and 0.002, respectively, vs. p=0.08 in the long-term (1 year)) • The Stevenson systematic review (HTA) concluded that KP performs significantly better in unblinded trials than CMT in terms of improving quality of life and reducing disability.	which include updated data from RCTs do not change the conclusions from the previous report (criteria A-1 or A3), nor provide major changes in the evidence (criteria B1-B4).

Key Question 1. What is the evidence of efficacy and effectiveness of vertebroplasty, kyphoplasty, and sacroplasty?			
Conclusions from CER Executive Summary	**New Sources of Evidence**	**New Findings**	**Conclusion from SRI**
Vertebroplasty (VP) vs. kyphoplasty (KP) • Efficacy: There is very low evidence from one poor-quality RCT that back pain scores improved equally (from 8.0 to 2.3-2.6) for PV and KP patients over 6 months • Effectiveness: There is low evidence from 12 cohort studies (6 prospective and 6 retrospective) that: • PV and KP led to comparable pain reduction (from 7.2-8.8 at baseline to 0.6-4.6) at follow-up periods up to 2 years in 8 of 10 studies. • PV and KP demonstrated comparable improvements (from 30.8-77 to 4.8-56) in the ODI at follow-up times up to 2 years in 4 of 5 studies	**Efficacy:** *Systematic Review*: Buchbinder (2015, Cochrane)[3] (3 new RCTs in addition to RCT included in previous report) **Effectiveness:** Not explored	**Efficacy**: No between-group differences in pain and disability (ODI), and QoL (EQ-5D) improvement over 1 mo. to 24 mos. follow-up observed in the systematic review;	• Updated analyses from the systematic review including new RCTs do not change the conclusions from the previous report (criteria A-1 or A3), nor provide major changes in the evidence (criteria B1-B4).
Sacroplasty ○ No comparative studies identified. There is very low	**Efficacy:** No comparative studies identified	○ No new RCT evidence	No new evidence

Key Question 1. What is the evidence of efficacy and effectiveness of vertebroplasty, kyphoplasty, and sacroplasty?			
Conclusions from CER Executive Summary	**New Sources of Evidence**	**New Findings**	**Conclusion from SRI**
evidence across four case series that suggests improvement in pain following sacroplasty.	**Effectiveness:** Not explored		

*Pathologic fractures may include multiple myeloma, hemangioma or metastases

Table 2. Vertebroplasty, Kyphoplasty, Sacroplasty Summary Table for Key Question 2.

Key Question 2: What is the evidence of the safety of vertebroplasty, kyphoplasty or sacroplasty?			
Conclusions from CER Executive Summary	**New Sources of Evidence**	**New Findings**	**Conclusion from SRI**
Vertebroplasty (VP) and Kyphoplasty (KP) There is low evidence for the following outcomes: • New fractures: ○ In comparative studies, the rate of new fractures at any location following PV, KP, or CMT was up to 25% at 6 months post-surgery, and up to 30% at 12 months, with no consistent pattern across studies in different rates for PV, KP, and CMT. ○ In cohort studies, from 22% to 66% of new fractures occurred in adjacent vertebrae, however, these rates are based on very small numbers. A systematic review concluded that the proportion of new fractures that were adjacent was higher for KP (75%) than for PV (52%). ○ Systematic reviews of case series report slightly higher rates of new fractures at any location for PV (16-	*Systematic Reviews:* Buchbinder (2015, Cochrane)[3] Li (2015)[6] Stevenson (2014)[7]	• New Fractures: ○ Buchbinder: VP vs. Sham or CMT: • At 12 months, clinically apparent vertebral fractures were more common in the PV group vs. control group but this was not statistically significant (19.6% vs. 13.8%; RR 1.47 [95% CI 0.39 to 5.50]); there was substantial statistical heterogeneity (I2 = 73%). No between-group differences in the number of new radiographic vertebral fractures at 12 or 24 months were reported. o Buchbinder: VP vs. KP • No between-group differences in the number of clinically apparent vertebral fractures [RR 1.32 (95% CI 0.91 to 1.92)] or new radiographic vertebral fractures at 12 or 24 months or adjacent level fractures at 6 months ○ Li; combined PV and KP vs. control • No between-group differences in risk of new or adjacent vertebral compression fractures • Cement Leakage ○ Stevenson	• New RCTs included in systematic reviews do not change the conclusions from the previous report (criteria A-2).

Key Question 2: What is the evidence of the safety of vertebroplasty, kyphoplasty or sacroplasty?			
Conclusions from CER Executive Summary	**New Sources of Evidence**	**New Findings**	**Conclusion from SRI**
21%) than for KP (7-17%). • Cement leakage ○ Rates of asymptomatic cement leakage are up to 80% for vertebroplasty and 50% for kyphoplasty. ○ Comparative studies and systematic reviews (consisting largely of case series) suggest that cement leakage is greater in PV than in KP; however, symptomatic leaks are rare (up to 1.6% in PV and 0.3% in KP; data from reviews of case series) • Pulmonary cement embolism (PCE) ○ One RCT reported a PCE rate for PV of 26%, with all cases asymptomatic ○ Systematic reviews of case series report pooled PCE rates from 0.1% to 1.7%, with insufficient information to compare rates for PV and KP.		• Cement leakage is common, particularly with PVP: pooled data from the RCTs indicate an incidence of 44% of treated vertebrae for PVP and 27% for BKP, while the case series indicate a range of 5 % to 72% for PVP and 9% to 18% for BKP; they do not report symptomatic and asymptomatic leakage separately. • Pulmonary Cement Embolism o Buchbinder: Reported that it was not possible to determine the rate of significant sequelae arising from cement leakage or embolism due to the small number of events. • Mortality ○ Li; combined PV and KP vs. control groups • No between-group differences in procedure-related or all-cause mortality o Buchbinder: • No deaths as a result of the procedure from the trials reviewed • Other adverse events: o Buchbinder: PV vs. sham or CMT • No between-group differences in the number of serious other adverse events for VP vs.	

Key Question 2: What is the evidence of the safety of vertebroplasty, kyphoplasty or sacroplasty?			
Conclusions from CER Executive Summary	**New Sources of Evidence**	**New Findings**	**Conclusion from SRI**
• Mortality: Data from systematic reviews primarily of case series ○ Rates in prospective studies of 2.1% (22/1051) for PV and 0.6% (24/5629) for retrospective studies. ○ Overall mortality for kyphoplasty ranging from 2.3% (13/588) to 3.2 % (25/522) from 2 different reviews ○ Perioperative mortality: 0.01% (1/406).		Sham (3/106 vs. 3/103; RR 1.01 [0.21 to 4.85 o Buchbinder: PV vs. KP • No significant between-group differences in the number of serious other adverse events	
Sacroplasty • There is very low evidence across four case series that the rate of cement leakage was 20.5% (7/34 patients)	No systematic reviews or RCTs identified	o No new evidence	No new evidence

Table 3. Vertebroplasty, Kyphoplasty, Sacroplasty Summary Table for Key Questions 3 and 4.

Key Question 3: What is the evidence that vertebroplasty, kyphoplasty or sacroplasty has differential efficacy or safety in subpopulations?			
Conclusions from CER Executive Summary	**New Sources of Evidence**	**New Findings**	**Conclusion from SRI**
Vertebroplasty (VP) vs. sham surgery or conservative treatment (CMT) There is very low evidence regarding the following: • Fracture age ○ No studies were designed to directly	*Systematic Reviews*: Buchbinder (2015, Cochrane)[3] Li (2015)[6]	Duration of pain: differential efficacy • Buchbinder: VP vs. Sham ○ No evidence of differential efficacy based on pre-procedural duration of pain ≤ 6 weeks vs. >6 weeks for	Findings from the systematic reviews and new RCTs do not change the conclusions from the previous report (criteria A-1 or A3), nor provide major changes in the

Key Question 3: What is the evidence that vertebroplasty, kyphoplasty or sacroplasty has differential efficacy or safety in subpopulations?			
Conclusions from CER Executive Summary	**New Sources of Evidence**	**New Findings**	**Conclusion from SRI**
compare efficacy or safety outcomes between patients with acute, subacute, and/or chronic fractures. ○ Two RCTs reported that improvements in pain and functional outcomes were not significantly different for patients with acute and chronic fractures; however, the studies may not have had adequate power for these post-hoc analyses. ○ One RCT of PV vs. CMT in patients with acute fractures reported greater improvement in pain and function for PV patients, but evidence for differential efficacy cannot be derived since there was no direct comparison with more chronic fractures in the same underlying population • Osteoporotic versus malignant fractures ○ Two retrospective cohort studies in patients with malignancy fractures cannot provide information for	*RCTs: trials in special populations not included in SR* Yang (2016)[8] Clark (2016)[4]	pain reduction or disability at 1-2 weeks, 1 month or for quality of life at 1 month; Tests for interaction between subgroups were not statistically significant. Fracture Age: differential efficacy • Li; VP and KP combined vs. control ○ No apparent evidence of differential efficacy based on fracture age <3 months vs. >3 months for pain reduction early (1 week to 1 month) mid-term (2-3 months) or longer term (12 months), based on qualitative assessment of stratum specific effect size estimates and their confidence intervals ; however, no test for interaction was provided; Special populations: Studies were not designed to evaluate differential efficacy or safety • Yang (RCT); PV vs. CMT in patients age ≥70 years ○ In aged patients with acute osteoporotic fractures and severe pain, early PV yielded faster, better pain relief and improved functional outcomes, which	evidence (criteria B1-B4).

Key Question 3: What is the evidence that vertebroplasty, kyphoplasty or sacroplasty has differential efficacy or safety in subpopulations?			
Conclusions from CER Executive Summary	**New Sources of Evidence**	**New Findings**	**Conclusion from SRI**
differential efficacy based on fracture etiology.		were maintained for 1 year. The overall complication rate following PV was significantly lower (16%) compared with CMT (35%) • Clark (RCT) PV vs. sham/placebo: Subanalysis of fracture age(≤ 3weeks vs. >3 weeks) does not appear to modify treatment with respect to proportion of patients achieving NRS score below 4 based on observed overlap of 95% CI, however no test for interaction was done and confidence intervals are wide. Fracture age ≤ 3weeks RD 31 (95% CI 12, 50), >3 weeks RD -4 (95% CI -39, 31). • Clark (RCT): Spine region may impact proportion of patients achieving NRS score below 4, however no test for interaction was provided: RD for thoracolumbar region, 48(95 %CI 27, 68), RD for non-thoracolumbar region -15 (95% CI -40, 9).	

Key Question 3: What is the evidence that vertebroplasty, kyphoplasty or sacroplasty has differential efficacy or safety in subpopulations?			
Conclusions from CER Executive Summary	**New Sources of Evidence**	**New Findings**	**Conclusion from SRI**
Kyphoplasty (KP) vs. conservative treatment (CMT) Very low evidence: No comparative studies were identified that assessed differential efficacy or safety according to patient, provider, or payer factors.	*New RCT:* Berenson (2011)[2]	• Berensen (RCT); KP vs. CMT in patients with metastatic (pathological) fractures only ○ At 1 month, KP was associated reduced pain, disability and use of medication; SF-36 PCS and MCS scores were improved following KP vs. CMT	New RCT does not change the conclusions from the previous report (criteria A-1 or A3), nor provide major changes in the evidence (criteria B1-B4). Findings are consistent with results in general population.
Vertebroplasty (VP) vs. kyphoplasty (KP) Very low evidence: • No comparative studies were identified that assessed differential efficacy or safety issues • Two retrospective cohort studies compared PV with KP among patients with fractures due to malignancy; one study reported comparable outcomes for PV and KP, and the other reported that KP led to more improvement in pain than PV over one year	No new evidence	No new evidence	No new evidence
Sacroplasty • Very low evidence: No comparative studies were identified	No new evidence	No new evidence	No new evidence.

Key Question 4: What are the cost implications and cost effectiveness of vertebroplasty, kyphoplasty and sacroplasty?			
Conclusions from CER Executive Summary	**New Sources of Evidence**	**New Findings**	**Conclusion from SRI**
<u>Vertebroplasty (PV) vs. sham surgery or conservative treatment (CMT)</u> Very low Evidence: • One RCT reported that PV was associated with significant increases in cost and Quality Adjusted Life Years (QALY) at one month, but that these increases were no longer statistically significant by one year. • One retrospective cohort study reported that cost per patient per one-point reduction in pain rating (0-10 scale) was not significantly different for PV patients and CMT patients	*HTA with cost utility analysis:* Stevenson (2014)[7]	• Stevenson: Authors report that no definitive conclusion on the cost-effectiveness of PVP or BKP can be provided given the uncertainty in the evidence base. Cost-effectiveness analyses were varied, with all of KP, PV and operative placebo with local anesthesia appearing the most cost-effective treatment dependent on the assumptions made regarding mortality effects, utility, hospitalization costs and operative placebo with local anesthesia costs	New cost-utility study does not change the conclusions from the previous report (criteria A-1 or A-3), nor provide major changes in the evidence (criteria B-1).
<u>Kyphoplasty (KP) vs. conservative treatment (CMT)</u> Very low evidence • Cost data from one RCT showed that KP was associated with increased cost and increased QALY compared with CMT.	*HTA with cost utility analysis:* Stevenson (2014)[7] *New analysis:* Fritzell (2011)[5] (additional analysis of previously included study)	• Stevenson: Authors report that no definitive conclusion on the cost-effectiveness of PVP or BKP can be provided given the uncertainty in the evidence base. Cost-effectiveness analyses were varied, with all of KP, PV and appearing the most cost-effective treatment dependent on the assumptions made regarding mortality effects, utility, hospitalization costs and operative placebo with local anesthesia costs. • Fritzell: Swedish participants ONLY from the FREE trial; 24 month follow-up data available. Conclusion: it was not possible	New cost-utility studies do not change the conclusions from the previous report (criteria A-1 or A-3), nor provide major changes in the evidence (criteria B-1).

Key Question 4: What are the cost implications and cost effectiveness of vertebroplasty, kyphoplasty and sacroplasty?			
Conclusions from CER Executive Summary	**New Sources of Evidence**	**New Findings**	**Conclusion from SRI**
		to demonstrate that KP was cost-effective compared with standard medical treatment in patients treated for an acute/subacute vertebral fracture due to osteoporosis.	
Cancer-related vertebral compression fractures • Vertebroplasty (PV) vs. non-surgical management • Kyphoplasty (KP) vs. non-surgical management **No evidence in 2010 report**	*New analysis:* Ontario HTA (2016)[1] on cancer-related VCF	• Ontario HTA: Systematic review clinical data are primarily from non-comparative studies of cancer-related VCF; only 1 of the included RCTs (Berenson described above) met our inclusion criteria. Conclusions are based on Markov models: Compared with nonsurgical management, PV and KP may be cost-effective at commonly accepted willingness to pay thresholds (ICERS of $17,870 and $33,471CAD respectively), however widespread use would increase healthcare costs to the system.	New economic study does not change the conclusions from the previous report (criteria A-1 or A-3), nor provide major changes in the evidence (criteria B-1) given the absence of evidence on efficacy in those with cancer-related compression fractures. Evidence is primarily from non-randomized, non-comparative studies.
Vertebroplasty (VP) vs. kyphoplasty (KP) No Evidence	No new evidence	No new evidence	No new evidence
Sacroplasty No Evidence	No new evidence	No new evidence	No new evidence

5. Conclusions

Vertebroplasty (PV)

- There are several systematic reviews containing updates to previously included RCTs and new RCTs published subsequent to the 2010 HTA. Not included in the systematic reviews are new RCT comparing PV with sham in persons with fractures of ≤ 6 weeks duration and one comparing PV with conservative care in persons >70 years old that were identified.
- Pooled estimates including updated data from previous RCTs reported in systematic reviews and one new RCT comparing safety and efficacy of **PV with sham** surgery suggest that PV may improve pain success in the short term (≤ 6 months) and this section of the report may benefit from being updated. In the longer term (> 6 months) updated RCT data are consistent with the original HTA and does not need updating
- Synthesized results from new trials comparing the safety and efficacy of **PV with conservative treatment** are consistent with the findings in the original HTA. This section does not need updating.
- Systematic reviews did not identify modification of treatment by duration of symptoms and modification by fracture age is not evident based on informal examination in the new trial of **PV versus sham**. Findings from one new trial of **PV versus conservative** care in patients aged ≥70 years are consistent with those in the general population in the original HTA; no update is needed.
- New economic analysis in osteoporotic vertebral compression fractures reports that no definitive conclusion regarding cost-effectiveness of PV is possible given the uncertainty in the evidence base. This is consistent with the original HTA; no update is needed.
- New economic analysis in patients with cancer-related vertebral compression fractures suggests that PV may be cost-effective compared with non-surgical management, however, data on clinical efficacy/effectiveness are based primarily on non-comparative observational studies. In the absence of efficacy data, this section does not need updating.

Kyphoplasty (KP)

- There are several systematic reviews that include updates to the previously included RCT published subsequent to the 2010 HTA.
- Updated data on efficacy and safety from the RCT comparing KP with conservative treatment are consistent with findings in the original HTA. This section does not need updating.
- Findings from the one new trial comparing KP with conservative treatment in patients with metastatic fractures are consistent with findings in the general population. No update is needed.
- One economic analysis reports that no definitive conclusion regarding cost-effectiveness of PV is possible given the uncertainty in the evidence base, the other reported that KP was not cost-effective versus conservative treatment. Findings are consistent with those in the original HTA. This section does not need updating.

- One new economic analysis in patients with cancer-related vertebral compression fractures suggests that KP may be cost-effective compared with non-surgical management, however, data on clinical efficacy/effectiveness appear to be based on primarily on non-comparative observational studies. In the absence of efficacy data, this section does not need updating.

Vertebroplasty(PV) versus Kyphoplasty (KP)

- There are several systematic reviews comparing the safety and efficacy of PV with KP that included three new RCTs.
- Synthesized results that include the new trials are consistent with findings in the original HTA. No update of this section is needed.

Sacroplasty

- There is no new comparative evidence on sacroplasty; the sections of the previous report dealing with this application are still valid and do not need updating.

REFERENCES

1. Vertebral Augmentation Involving Vertebroplasty or Kyphoplasty for Cancer-Related Vertebral Compression Fractures: A Systematic Review. Ont Health Technol Assess Ser 2016;16:1-202.
2. Berenson J, Pflugmacher R, Jarzem P, et al. Balloon kyphoplasty versus non-surgical fracture management for treatment of painful vertebral body compression fractures in patients with cancer: a multicentre, randomised controlled trial. Lancet Oncol 2011;12:225-35.
3. Buchbinder R, Golmohammadi K, Johnston RV, et al. Percutaneous vertebroplasty for osteoporotic vertebral compression fracture. Cochrane Database Syst Rev 2015;4:CD006349.
4. Clark W, Bird P, Gonski P, et al. Safety and efficacy of vertebroplasty for acute painful osteoporotic fractures (VAPOUR): a multicentre, randomised, double-blind, placebo-controlled trial. Lancet 2016;388:1408-16.
5. Fritzell P, Ohlin A, Borgstrom F. Cost-effectiveness of balloon kyphoplasty versus standard medical treatment in patients with osteoporotic vertebral compression fracture: a Swedish multicenter randomized controlled trial with 2-year follow-up. Spine (Phila Pa 1976) 2011;36:2243-51.
6. Li L, Ren J, Liu J, et al. Results of Vertebral Augmentation Treatment for Patients of Painful Osteoporotic Vertebral Compression Fractures: A Meta-Analysis of Eight Randomized Controlled Trials. PLoS One 2015;10:e0138126.
7. Stevenson M, Gomersall T, Lloyd Jones M, et al. Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for the treatment of osteoporotic vertebral fractures: a systematic review and cost-effectiveness analysis. Health Technol Assess 2014;18:1-290.
8. Yang EZ, Xu JG, Huang GZ, et al. Percutaneous Vertebroplasty Versus Conservative Treatment in Aged Patients with Acute Osteoporotic Vertebral Compression Fractures: A Prospective Randomized Controlled Clinical Study. Spine (Phila Pa 1976) 2016;41:653-60.

APPENDIX A. SEARCH STRATEGIES

Below is the search strategy for PubMed.

Search dates March 1, 2010 through November 26, 2016

General Search

	General Search
#1	Search **vertebroplast* OR kyphoplast* OR sacroplast* OR vesselplast* OR skyphoplast* OR vertebral augmentation** Filters: **Abstract; Publication date from 2016/03/01; English**
#2	Search **(#72)NOT cadaver* NOT sheep** Filters: **Abstract; Publication date from 2016/03/01; English**

Safety Search

	Safety Search
#1	Search **vertebroplast* OR kyphoplast* OR sacroplast* OR vesselplast* OR skyphoplast* OR vertebral augmentation**
#2	Search **(#1)NOT cadaver* NOT sheep**
#3	Search **(#2) AND (safety or complication or complications or adverse)**
#4	Search **(#2) AND (safety or complication or complications or adverse)** Filters: **Abstract; Publication date from 2016/03/01; English**
#5	Search **(#2) AND ("cement leakage" OR "cement leak")** Filters: **Abstract; Publication date from 2016/03/01; English**
#6	**(#2) AND (emboli*)** Filters: **Abstract; Publication date from 2016/03/01; English**
#8	Search **(#2) AND ("adjacent fracture" or "new fracture" or "subsequent fracture")** Filters: **Abstract; Publication date from 2016/03/01; English**

Cost-effectiveness search

	Cost effectiveness search
#1	Search **vertebroplast* OR kyphoplast* OR sacroplast* OR vesselplast* OR skyphoplast* OR vertebral augmentation OR percutaneous vertebral augmentation OR cement augmentation** Filters: **Abstract; Publication date from 2016/03/01; English**
#2	Search **(#1)NOT cadaver* NOT sheep** Filters: **Abstract; Publication date from 2016/03/01; English**
#3	**(#2) AND (economic OR cost OR cost-effectiveness OR cost-benefit OR cost-utility)** Filters: **Abstract; Publication date from 2016/03/01; English**

APPENDIX B. SUMMARY OF INCLUDED SYSTEMATIC REVIEWS.

Assessment (year) Search dates	Purpose	Condition	Treatments vs. controls	Primary Outcomes	Evidence-base Used	Primary Conclusions
Buchbinder 2015 (Cochrane)	To synthesize the available evidence regarding the benefits and harms of vertebroplasty for treatment of osteoporotic vertebral fractures.	Osteoporotic vertebral fractures	VP vs. sham, CC, or KP	Pain, disability, disease-specific and overall health-related quality of life, patient-reported treatment success, new symptomatic vertebral fractures, serious adverse events	**VP vs. sham:** 2 RCTs (n=209) **VP vs. CC:** 6 RCTs (n=566) **VP vs. KP:** 3 RCTs, 1 quasi-RCT (n=545)	**VP vs. sham (efficacy):** No between-group differences in any efficacy outcome (pain, disability, quality of life) at any timepoint. **VP vs. CC (efficacy):** VP superior to CC in pain and disability improvement up to 12 months and for quality of life up improvement up to 3 months follow-up. **VP vs. sham or CC (safety)**: More new clinically apparent vertebral fractures at 12 months in the VP vs. the sham/ CC group but the difference was not statistically significant; no between-group differences in the number of new radiographic vertebral fractures at 12 or 24 months or in the number of other serious adverse events. **VP vs. KP:** No between-group differences in pain, disability and quality of life improvement up to

Assessment (year) Search dates	Purpose	Condition	Treatments vs. controls	Primary Outcomes	Evidence-base Used	Primary Conclusions
						24 months, or new clinical or radiographic vertebral fractures at 12 or 24 months, or adjacent level fractures at 6 months follow-up.
Li 2015	To compare clinical differences in pain relief, spinal functional outcomes, and overall quality of life between vertebral augmentation and control treatment for painful osteoporotic vertebral compression fractures	Osteoporotic vertebral fractures	VP or KP vs. sham or CC	Pain relief*	**VP vs. sham:** 2 RCTs (n=209) **VP vs. CC:** 5 RCTs (n=478) **KP vs. CC** 1 RCT (n=300)	**VP vs. sham (efficacy):** No differences between groups in early- and mid-term pain relief (no long-term data). **VP vs. CC (efficacy):** VP resulted in greater pain relief than CC at all time-points but only mid- and long-term were significant (p=0.003 and 0.000, respectively, vs. p=0.06 in the early-term). **KP vs. CC (efficacy):** KP resulted in greater pain relief than CC at all time-points but only early- and mid-term were significant (p=0.000 and 0.002, respectively, vs. p=0.08 in the long-term) **VP/KP vs. sham/CC (safety):** No difference in risk of new or adjacent vertebral compression fractures or of

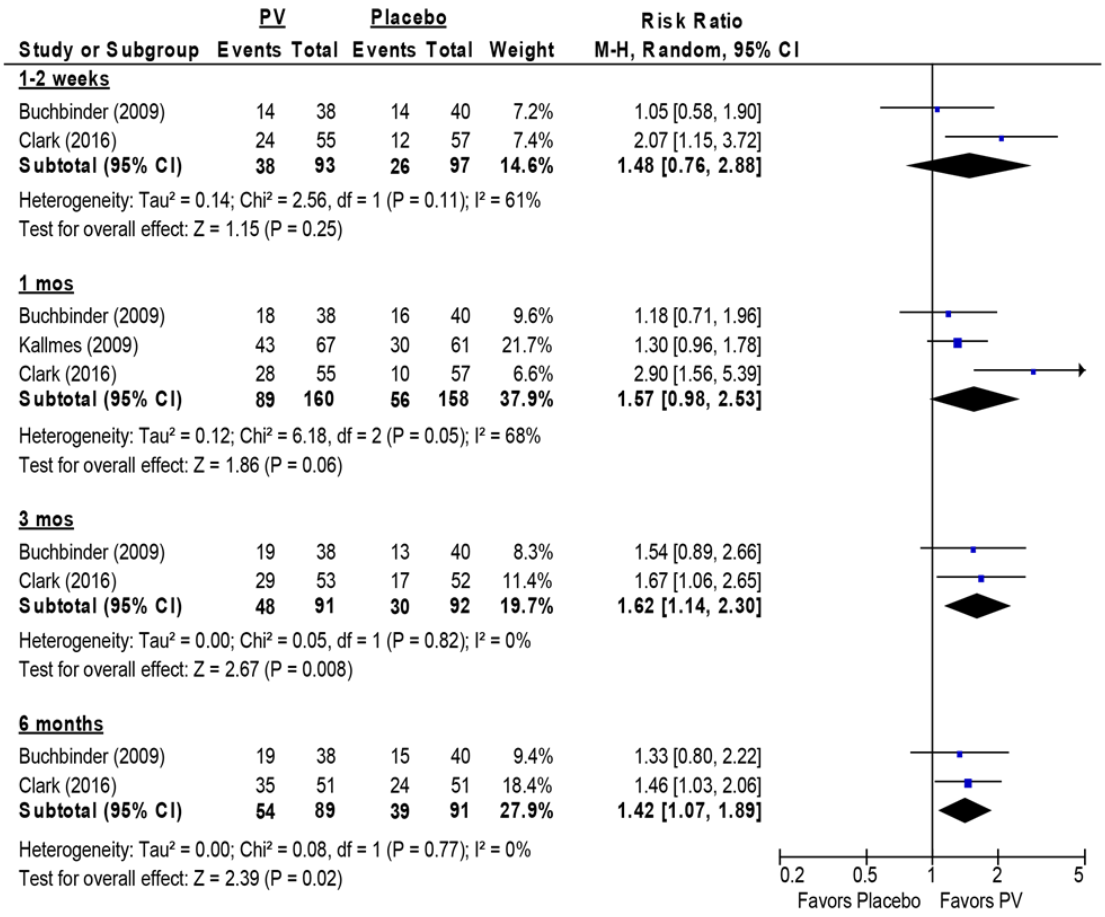
Assessment (year) Search dates	Purpose	Condition	Treatments vs. controls	Primary Outcomes	Evidence-base Used	Primary Conclusions
						procedure-related or all-cause mortality
Stevenson 2014	To systematically evaluate and appraise the clinical effectiveness and cost-effectiveness of VP and percutaneous KP in reducing pain and disability in people with osteoporotic vertebral compression fractures in England and Wales	Osteoporotic vertebral fractures	VP or KP vs. sham or CC or each other	Health-related quality of life, back-specific functional status/ mobility, pain/analgesic use	**VP vs. sham:** 2 RCTs (n=209) **VP vs. CC:** 5 RCTs (n=505) **KP vs. CC** 1 RCT (n=300) **VP vs. KP** 1 RCT (n=100) **Cost-effectiveness** 1 study (hypo-thetical patient cohort); 2 models presented by industry (Johnson & Johnson, Medtronic)	**VP vs. sham:** There is as yet no convincing evidence that either VP performs better than sham. **VP vs. CC:** VP perform significantly better in unblinded trials than CC in terms of improving quality of life and reducing pain and disability **KP vs. CC:** KP perform significantly better than CC in terms of improving quality of life and reducing pain and disability **VP vs. KP:** No difference in pain between groups; function and quality of not assessed **Cost-effectiveness:** The uncertainty in the evidence base means that no definitive conclusion on the cost-effectiveness of VP or KP can be provided.

CC: conservative care; KP: Kyphoplasty; RCTs: randomized controlled trials; VP: vertebroplasty.

*Only outcome for which results were reported stratified by comparison groups of interest (as opposed to the combined groups of VP/KP vs. sham/CC).

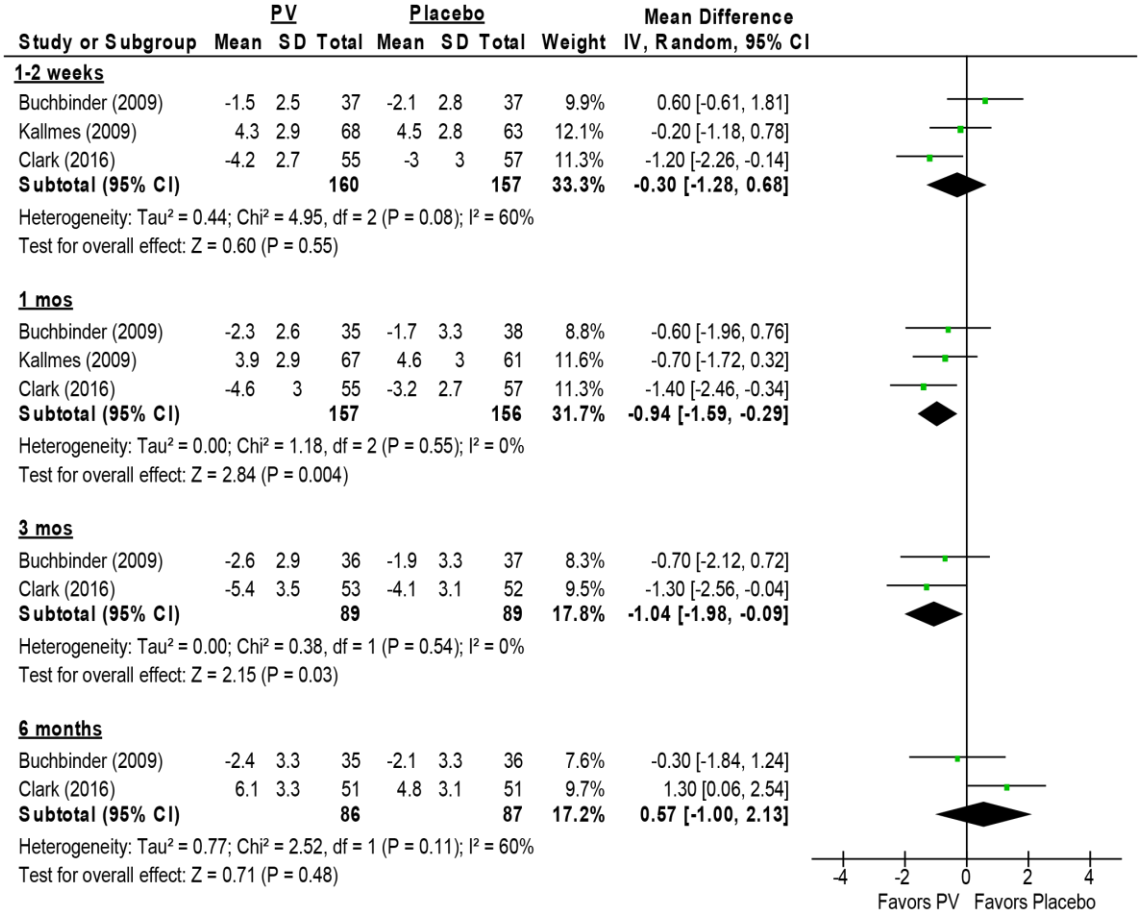
APPENDIX C. PRELIMINARY META-ANALYSES: PV vs. SHAM

Figure 1. Success: Proportion of patients with improvement in pain*



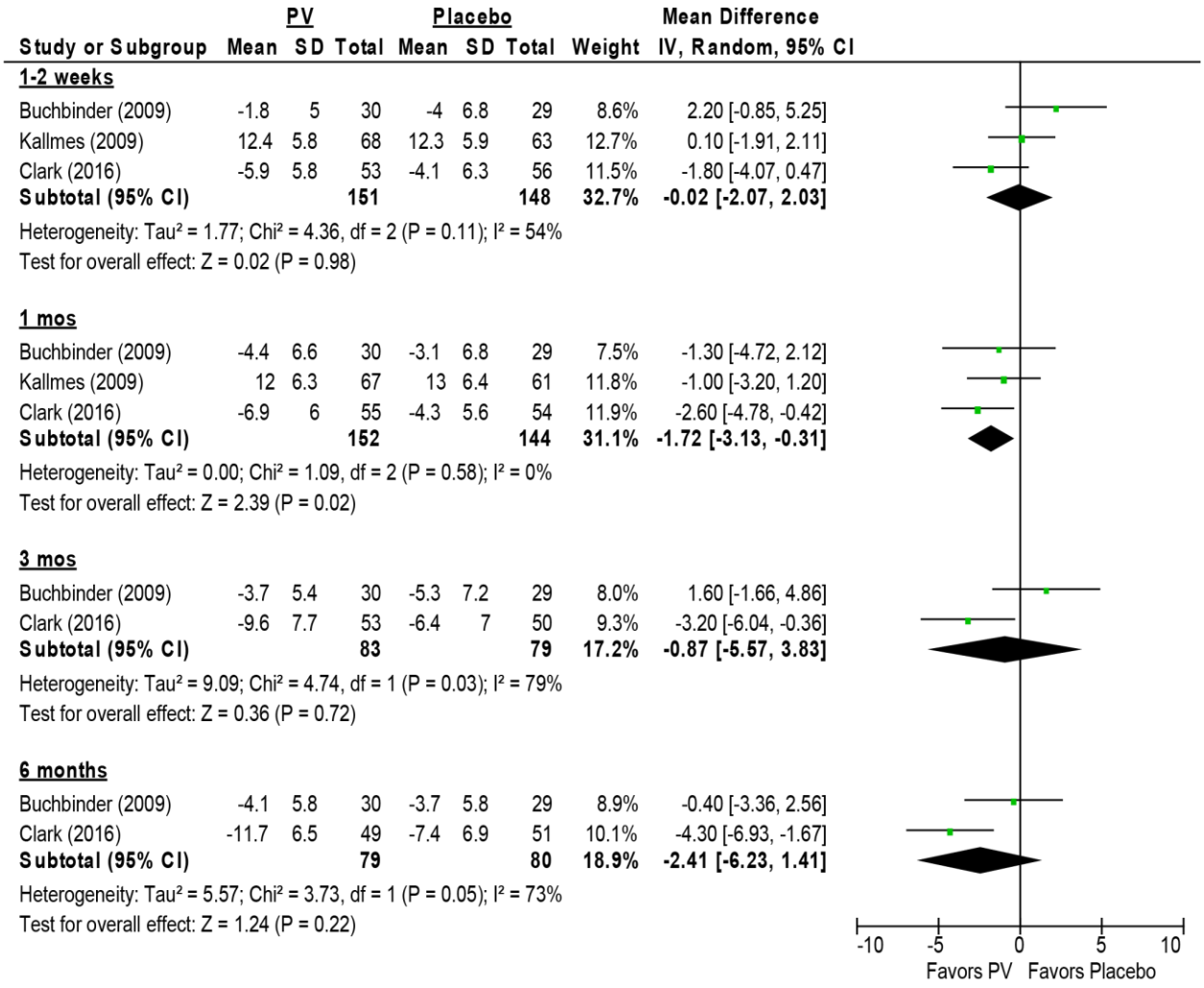
*Improvement in pain was defined variably across the three trials: 2.5 units (Buckbinder) or >30% or more from baseline (Kallmes) or pain less than 4 out of 10 (Clark)

Figure 2: Mean Difference in Pain Scores (VAS or NRS*)



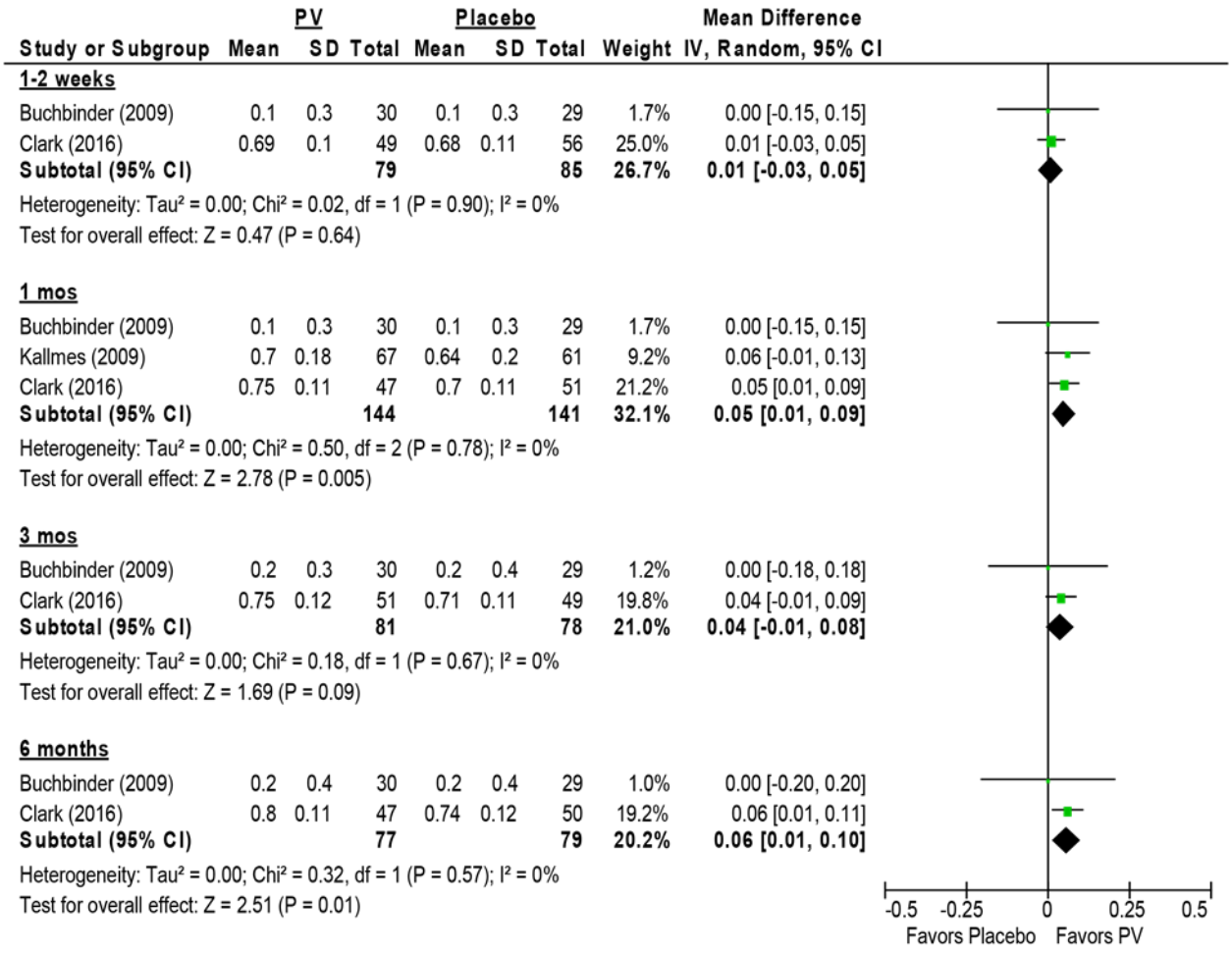
* O-10 point scale, 10 being worst pain; Buchbinder Cochrane review considered clinically important change to be 1.5 points

Figure 3: Mean Difference in Roland-Morris Disability Questionnaire (RMDQ) Scores*



*RMDQ range 0-23 points; higher score, worse disability. Buchbinder Cochrane review considered clinically important change to be 2-3 points

Figure 4: Mean difference in EQ5D*



Buchbinder Cochrane review considered clinically important change to be 0.074 on 0-1.0 EQ-5D

APPENDIX D. PUBLICATIONS EXCLUDED AT FULL TEXT REVIEW

Excluded systematic reviews

Citation	Reason for exclusion
Bouza C, Lopez-Cuadrado T, Almendro N, Amate JM. Safety of balloon kyphoplasty in the treatment of osteoporotic vertebral compression fractures in Europe: a meta-analysis of randomized controlled trials. Eur Spine J 2015;24:715-23.	Safety of kyphoplasty only; included trials of non-FDA approved devices
Chang X, Lv YF, Chen B, Li, HY, Han XB, Yang K, Zhang W, Zhou Y, Li CQ. Vertebroplasty versus kyphoplasty in osteoporotic vertebral compression fracture: a meta-analysis of prospective comparative studies. Int Orthop 2015;39:491-500.	Combined RCTs and observational studies
De la Garza-Ramos R, Benvenutti-Regato M, Caro-Osorio E. Vertebroplasty and kyphoplasty for cervical spine metastases: a systematic review and meta-analysis. Int J Spine Surg 2016;10:7.	Systematic review of case series only
Fan B, Wei Z, Zhou X, et al. Does vertebral augmentation lead to an increasing incidence of adjacent vertebral failure? A systematic review and meta-analysis. *Int J Surg.* 2016	Analysis of adjacent fractures only; Substantial overlap with Buchbinder SR with same conclusions; Poor documentation of included studies
Gu CN, Brinjikji W, Evans AJ, Murad MH, Kallmes DF. Outcomes of vertebroplasty compared with kyphoplasty: a systematic review and meta-analysis. J Neurointerv Surg 2015;11	Combined RCTs and observational studies
Han SL, Wan SL, Li QT, Xu DT, Zang HM, Chen NJ, Chen LY, Zhang WP, Luan C, Yang F, Xu ZW. Is vertebroplasty a risk factor for subsequent vertebral fracture, meta-analysis of published evidence? Osteoporos Int 2015;26:113-22.	Combined RCTs and observational studies
Liu J, Li X, Tang D, Ciu X, Li X, Yao M, Yu P, Qian X, Wang Y, Jiang H. Comparing pain reduction following vertebroplasty and conservative treatment for osteoporotic vertebral compression fractures: a meta-analysis of randomized controlled trials. Pain Physician 2013;16:455-64.	Not the most up to date systematic review identified (i.e., did not included all relevant RCTs published to date)
Mattie R, Laimi K, Yu S, Saltychev M. Comparing Percutaneous Vertebroplasty and Conservative Therapy for Treating Osteoporotic Compression Fractures in the Thoracic and Lumbar Spine: A Systematic Review and Meta-Analysis. J Bone Joint Surg Am. 2016;98(12):1041-1051	Includes same RCTs and data as Buchbinder SR with same conclusions
Vertebral Augmentation Involving Vertebroplasty or Kyphoplasty for Cancer-Related Vertebral Compression Fractures: A Systematic Review. Ont Health Technol Assess Ser. 2016;16(11):1-202.	Systematic review portion: primarily non-comparative studies of cancer-related VCF; 6 RCTs included, only 1 of which would meet inclusion criteria and is captured in the update report.
Yuan WH, Hsu HC, Lai KL. Vertebroplasty and balloon kyphoplasty versus conservative treatment for osteoporotic vertebral compression fractures: A meta-analysis. *Medicine (Baltimore).* 2016;95(31):e4491	Includes almost all the same RCTs as Buchbinder ,Li and Stevenson SRs; Buchbinder and Stevenson analyses higher quality, more thorough;
Zhao G, Liu X, Li F. Balloon kyphoplasty versus percutaneous vertebroplasty for treatment of osteoporotic vertebral compression fractures (OVCFs). Osteoporos Int. 2016;27(9):2823-2834.	Combines 1 RCT and 10 nonrandomized comparative studies;

Excluded randomized controlled trials

Citation	Reason for exclusion
Arabmotlagh M, Rickert M, Lukas A, Rauschmann M, Fleege C. Small cavity creation in the vertebral body reduces the rate of cement leakage during vertebroplasty. J Orthop Res 2016;26.	Comparison of techniques
Blasco J, Martinez-Ferrer A, Macho J, San Roman L, Pomes J, Carrasco J, Monegal A, Guanabens N, Peris P. Effect of vertebroplasty on pain relief, quality of life, and the incidence of new vertebral fractures: a 12-month randomized follow-up, controlled trial. J Bone Miner Res 2012;27:1159-66.	Included in the systematic review by Buchbinder 2015
Boonen S, Van Meirhaeghe J, Bastian L, Cummings SR, Ranstam J, Tillman JB, Eastell R, Talmadge K, Wardlaw D. Balloon kyphoplasty for the treatment of acute vertebral compression fractures: 2-year results from a randomized trial. J Bone Miner Res 2011;26:1627-37.	Included in the systematic reviews by Li 2015 and Stevenson 2014
Chen D, An ZQ, Song S, Tang JF, Qin H. Percutaneous vertebroplasty compared with conservative treatment in patients with chronic painful osteoporotic spinal fractures. J Clin Neurosci 2014;21:473-7.	Included in the systematic review by Buchbinder 2015
Comstock BA, Sitlani CM, Jarvik JG, Heagerty PJ, Turner JA, Kallmes DF. Investigational vertebroplasty safety and efficacy trial (INVEST): patient-reported outcomes through 1 year. Radiology 2013;269:224-31.	Included in the systematic review by Buchbinder 2015
Dohm M, Black CM, Dacre A, Tillman JB, Fueredi G. A randomized trial comparing balloon kyphoplasty and vertebroplasty for vertebral compression fractures due to osteoporosis. AJNR Am J Neuroradiol 2014;35:2227-36.	Included in the systematic review by Buchbinder 2015
Endres S, Badura A. Shield kyphoplasty through a unipedicular approach compared to vertebroplasty and balloon kyphoplasty in osteoporotic thoracolumbar fracture: a prospective randomized study. Orthop Traumatol Surg Res 2012;98:334-40.	Included in the systematic review by Buchbinder 2015
Evans AJ, Kip KE, Brinjikji W, Layton KF, Jensen ML, Gaughen JR, Kallmes DF. Randomized controlled trial of vertebroplasty versus kyphoplasty in the treatment of vertebral compression fractures. J Neurointerv Surg 2015;24	Sufficient data from systematic reviews for this comparison (VP vs. conservative); single RCT not included (conclusions consistent with SRs) Epub version of citation below
Evans AJ, Kip KE, Brinjikji W, et al. Randomized controlled trial of vertebroplasty versus kyphoplasty in the treatment of vertebral compression fractures. J Neurointerv Surg. 2016;8(7):756-763.	Final citation for Evans study; Sufficient data from systematic reviews for this comparison (VP vs. conservative); single RCT not included (conclusions consistent with SRs)
Farrokhi MR, Alibai E, Maghami Z. Randomized controlled trial of percutaneous vertebroplasty versus optimal medical management for the relief of pain and disability in acute osteoporotic vertebral compression fractures. J Neurosurg Spine 2011;14:561-9.	Included in the systematic review by Buchbinder 2015
Korovessis P, Vardakastanis K, Vitsas V, Syrimpeis V. Is Kiva implant advantageous to balloon kyphoplasty in treating osteolytic metastasis to the spine? Comparison of 2 percutaneous minimal invasive spine techniques: a prospective randomized controlled short-term study. Spine (Phila Pa 2014;39:E231-9.	Comparison of techniques

Citation	Reason for exclusion
Korovessis P, Vardakastanis K, Repantis T, Vitsas V. Balloon kyphoplasty versus KIVA vertebral augmentation--comparison of 2 techniques for osteoporotic vertebral body fractures: a prospective randomized study. Spine (Phila Pa) 2013;38:292-9.	Comparison of techniques
Kroon F, Staples M, Ebeling PR, Ebeling PR, Wark JD, Osborne RH, Mitchell PJ, Wriedt CH, Buchbinder R. Two-year results of a randomized placebo-controlled trial of vertebroplasty for acute osteoporotic vertebral fractures. J Bone Miner Res 2014;29:1346-55.	Included in the systematic review by Buchbinder 2015
Noriega DC, Ramajo RH, Lite IS, Toribio B, Corredera R, Ardura F, Kruger A. Safety and clinical performance of kyphoplasty and SpineJack procedures in the treatment of osteoporotic vertebral compression fractures: a pilot, monocentric, investigator-initiated study. Osteoporos Int 2016;8:8.	Comparator not FDA approved; Comparison of techniques
Peris P, Blasco J, Carrasco JL, Martinez-Ferrer A, Macho J, San Roman L, Monegal A, Guanabens N. Risk factors for the development of chronic back pain after percutaneous vertebroplasty versus conservative treatment. Calcif Tissue Int 2015;96:89-96.	Sufficient data from systematic reviews for fracture age and duration of symptoms; single RCT not included (conclusions consistent with SRs)
Petersen A, Hartwig E, Koch EM, Wollny M. Clinical comparison of postoperative results of balloon kyphoplasty (BKP) versus radiofrequency-targeted vertebral augmentation (RF-TVA): a prospective clinical study. Eur J Orthop Surg Traumatol 2016;26:67-75.	Comparison of techniques
Staples MP, Howe BM, Ringler MD, Mitchell P, Wriedt CH, Wark JD, Ebeling PR, Osborne RH, Kallmes DF, Buchbinder R. New vertebral fractures after vertebroplasty: 2-year results from a randomised controlled trial. Arch Osteoporos 2015;10:229.	Same population as an RCT included in the systematic review by Buchbinder 2015
Tutton SM, Pflugmacher R, Davidian M, Beall DP, Facchini FR, Garfin SR. KAST Study: The Kiva System As a Vertebral Augmentation Treatment-A Safety and Effectiveness Trial: A Randomized, Noninferiority Trial Comparing the Kiva System With Balloon Kyphoplasty in Treatment of Osteoporotic Vertebral Compression Fractures. Spine (Phila Pa 2015;40:865-75.	Comparison of techniques
Van Meirhaeghe J, Bastian L, Boonen S, Ranstam J, Tillman JB, Wardlaw D. A randomized trial of balloon kyphoplasty and nonsurgical management for treating acute vertebral compression fractures: vertebral body kyphosis correction and surgical parameters. Spine (Phila Pa 2013;38:971-83.	Included in the systematic review by Li 2015
Vogl TJ, Pflugmacher R, Hierholzer J, Stender G, Gounis M, Wakhloo A, Fiebig C, Hammerstingl R. Cement directed kyphoplasty reduces cement leakage as compared with vertebroplasty: results of a controlled, randomized trial. Spine (Phila Pa 2013;38:1730-6.	Included in the systematic review by Buchbinder 2015
Wang B, Guo H, Yuan L, Huang D, Zhang H, Hao D. A prospective randomized controlled study comparing the pain relief in patients with osteoporotic vertebral compression fractures with the use of vertebroplasty or facet blocking. Eur Spine J 2016;5:5.	Sufficient data from systematic reviews for this comparison (VP vs. conservative); single RCT not included (conclusions consistent with SRs)
Wang CH, Ma JZ, Zhang CC, Nie L. Comparison of high-viscosity cement vertebroplasty and balloon kyphoplasty for the treatment of osteoporotic vertebral compression fractures. Pain Physician 2015;18:E187-94.	Comparison of techniques

Citation	Reason for exclusion
Werner CM, Osterhoff G, Schlickeiser J, Jenni R, Wanner GA, Ossendorf C, Simmen HP. Vertebral body stenting versus kyphoplasty for the treatment of osteoporotic vertebral compression fractures: a randomized trial. J Bone Joint Surg Am 2013;95:577-84.	Comparator not FDA approved; Comparison of techniques
Yi X, Lu H, Tian F, Wang Y, Li C, Liu H, Liu X, Li H. Recompression in new levels after percutaneous vertebroplasty and kyphoplasty compared with conservative treatment. Arch Orthop Trauma Surg 2014;134:21-30.	Data combined for the vertebroplasty and kyphoplasty groups

Excluded economic studies

Citation	Reason for exclusion
Becker S, Pfeiffer KP, Ogon M. Comparison of inpatient treatment costs after balloon kyphoplasty and non-surgical treatment of vertebral body compression fractures. Eur Spine J 2011;20:1259-64.	Costing study; not a formal economic analysis
Takura T, Yoshimatsu M, Sugimori H, et al. Cost-Effectiveness Analysis of Percutaneous Vertebroplasty for Osteoporotic Compression Fractures. *Clin Spine Surg.* 2016	Single arm (PV only) study; evaluated change from baseline at 52 weeks; not comparative with other treatment

APPENDIX E. NEW FDA APPROVED DEVICES

Procedure/Device	Brief description	FDA Approval (Date)	Source
KIVA for VCF (Benvenue Medical, Santa Clara, CA)	A small coil-like flexible implant placed in the vertebral body that restores vertebral height and allows the direction of bone cement into the space surrounding the implant	FDA 510(k) clearance (January 2014)	http://benvenuemedical.com/products/ http://benvenuemedical.com/press-release/kiva-vcf-treatment-system-receives-fda-clearance-vertebral-compression-fractures/
Radiofrequency-targeted vertebral augmentation (RFTVA) (DFINE StabiliT San Jose, CA)	Targeted delivery of radiofrequency-activated warm, highly viscous bone cement PMMA using an articulating osteotome	510k approved (December 2009)	https://www.accessdata.fda.gov/cdrh_docs/pdf9/K090986.pdf
High-Viscosity cement vertebroplasty (HVCV) Confidence Spinal Cement System (DePuy Spine Inc, Raynham, MA, USA)	Modification of vertebroplasty designed to decrease cement leakage	FDA 510(k) clearance (December 2011)	https://www.accessdata.fda.gov/cdrh_docs/pdf11/K112907.pdf
Shield Kyphoplasty SOTEIRA, INC. 5 Whitcomb Avenue Ayer, MA 01432	includes a unilateral, steerable cavity creator and a self-expanding stent-like implant designed to direct PMMA cement flow for optimal placement during vertebral augmentation.	FDA 510(k) clearance (December 2011)	http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K093477
Crosstrees PVA Pod System	Uses a soft woven fabric pod that allows the flow of bone cement to be controlled as it is injected into the vertebral body.	FDA 510(k) clearance (August 2013)	https://www.accessdata.fda.gov/cdrh_docs/pdf13/K130089.pdf http://xtreesmed.com/crosstrees-system-solution.php

Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy: An Evidence Update

Evidence Update for the Washington State Health Technology Assessment Program

January 2017

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Bottom Line Conclusion

A review of the studies published since the original evidence review conducted in March 2012 does not provide sufficient evidence to amend the current coverage policy for stereotactic radiation surgery (SRS) and stereotactic body radiation therapy (SBRT), as adopted by the Health Technology Clinical Committee in March 2013. The current review did not find sufficient evidence to indicate that SRS or SBRT is an effective treatment for any cancer that is not already included in the coverage policy. Likewise, there is not sufficient evidence to indicate that SRS or SBRT are ineffective for the cancers that are currently covered.

Background

The Washington State Health Technology Clinical Committee completed an evidence review in 2012 on the effectiveness of SRS and SBRT for treating various cancers. On March 22, 2013, the committee adopted the following coverage determination:

- SRS for central nervous system (CNS) primary and metastatic tumors is a covered benefit for adults and children when the following criteria are met:
  - Patient functional status score (i.e., Karnofsky score) is greater than or equal to 50; and
  - Evaluation includes multidisciplinary team analysis (e.g., tumor board), including surgical input.
- SBRT is covered for adults and children for the following conditions when the following criteria are met:
  - For cancers of spine/paraspinal structures: or
  - For inoperable non-small cell lung cancer, stage 1; and
  - Evaluation includes multidisciplinary team analysis (e.g., tumor board), including surgical input.

The Washington Health Technology Assessment program contracted with the Center for Evidence-based Policy (Center) to conduct an updated evidence search on this topic and produce a brief on the included eligible studies to help determine whether the previous coverage policy decision should be reviewed.

Methods

To identify studies published since the 2012 evidence review, Center researchers conducted a literature search using Ovid MEDLINE®, Cochrane Database of Systematic Reviews, and Cochrane Controlled Trials Register database. The search strategies for each database are in Appendix A.

Studies were included if they met the criteria outlined in the PICO below and the following inclusion criteria by location of tumor for individual studies:

- Treatments delivered in 10 or fewer fractions

- Published, peer-reviewed, English-language articles
- Systematic reviews, technology assessments, randomized controlled trials (RCTs), and non-randomized, comparative study designs (prospective, retrospective, and controlled clinical trials)

The following are additional inclusion criteria for individual studies specifically:

- Eligible study design with a minimum sample size of 20 participants for CNS cancers
- Eligible study design with a minimum sample size of 50 participants for cancers of the breast, colon, head and neck, lung, and prostate
- Eligible study design with a minimum sample size of 20 participants for other non-CNS cancers
- All relevant economic evaluations, cost-effectiveness analyses, and economic simulation models

For interpretation of findings from economic analyses, Center researchers used the generally accepted willingness to pay threshold of $100,000 per quality-adjusted life-year (QALY) (Neumann, Cohen, & Weinstein, 2014).

PICO

Populations:

Adults and children with CNS and non-CNS malignancies for which treatment with radiation therapy is appropriate

Interventions:

SRS or SBRT with devices such as Gamma Knife®, CyberKnife®, TomoTherapy®

Comparators:

Conventional (conformal) external beam radiation therapy (EBRT), surgery, no treatment

Outcomes:

Survival rate, duration of symptom-free remission, quality of life, harms including radiation exposure and complications, cost, cost-effectiveness

Key Questions

1. What is the evidence of effectiveness for SRS and SBRT compared to conventional EBRT for the following patients:
    a. Patients with CNS tumors?
    b. Patients with non-CNS cancers?

2. What are the potential harms of SRS and SBRT compared to conventional EBRT? What is the incidence of these harms? Include consideration of progression of treatment in unnecessary or inappropriate ways.

3. What is the evidence that SRS and SBRT have differential efficacy or safety issues in subpopulations? Include consideration of the following characteristics:
    a. Gender
    b. Age
    c. Site and type of cancer
    d. Stage and grade of cancer
    e. Setting, provider characteristics, equipment, quality assurance standards and procedures

4. What is the evidence of cost and cost-effectiveness of SRS and SBRT compared to EBRT?

Findings

After de-duplication, 1,968 documents were found in the searches, including 1,808 from Ovid MEDLINE®, 139 from Cochrane Central Register of Controlled Trials, and 21 from Cochrane Database of Systematic Reviews. After title and abstract screening by CM and VK, out of the 1,968 documents, 154 were identified for full-text review. After full-text review, CM and VK determined that 83 studies were eligible for this evidence update (Figure 1). Table 1 shows the number of included articles by cancer and type of study.

Figure 1: Searching and Screening of Eligible Studies

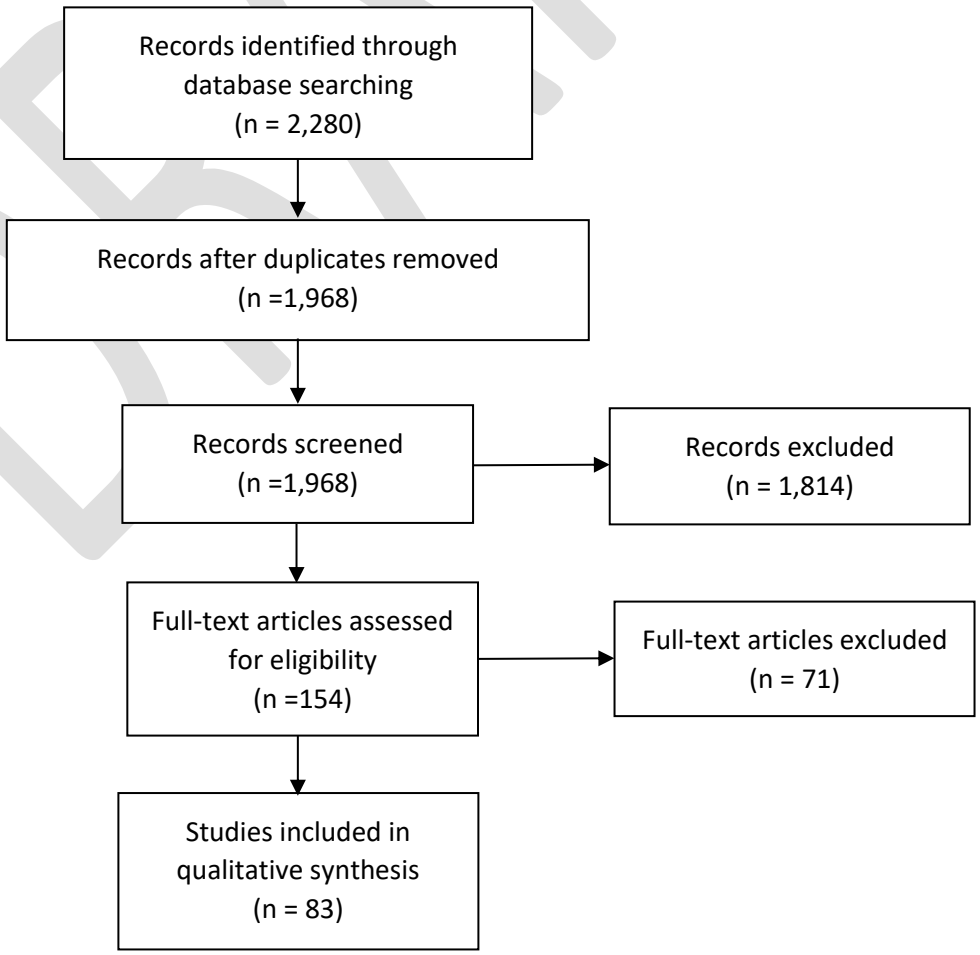

Table 1: Number of Included Articles by Cancer and Type of Study

Cancer	Total	Systematic Reviews & Meta-Analysis	Randomized Controlled Studies	Comparative and Other Studies	Cost-Effectiveness Studies
Brain Cancer	31	8	6	14	3
Non-Small-Cell Lung Cancer	29	5	2	21	1
Prostate Cancer	7	1	0	5	1
Pancreatic Cancer	2	1	0	1	0
Liver Cancer	3	0	0	3	0
Spinal Cancer	3	0	0	2	1
Adrenal Cancer	1	1	0	0	0
Cancers with single comparative study	7	0	0	7*	0
TOTAL	**83**	**16**	**8**	**53**	**6**

**Single comparative studies were identified for each of these seven cancers: cervical (Gill et al., 2014), extracranial oligometastases (Kao, Timmins, Ozao-Choy, & Packer, 2016), juxtapapillary choroidal melanoma (Krema et al., 2013), oropharyngeal (Al-Mamgani et al., 2013), pulmonary metastases from osteosarcoma (W. Yu et al., 2014), recurrent atypical meningiomas (Talacchi et al., 2016), and malignancy anywhere in the body after SRS (Rahman et al., 2014).*

Brain Cancer

There is some additional evidence to support the conclusion that SRS is an effective treatment for brain cancer. The most recent systematic review is an update to the Cochrane systematic review that examined SRS plus whole brain radiation therapy (WBRT) versus WBRT alone for the treatment of brain metastases (Patil et al., 2016). The authors conducted meta-analyses for overall survival, median survival, and local failure using two trials with a total of 358 participants. Patil et al. (2016) found a non-significant reduction in overall survival in the SRS+WBRT group compared to the WBRT group, although the difference between groups was close to statistical significance (hazard ratio [HR], 0.82, 95% confidence interval [CI], 0.65 to 1.02; p = .08). For patients with one brain metastasis, median survival was significantly longer in SRS+WBRT compared to WBRT alone (6.5 months vs. 4.9 months; p = .04) (Patil et al., 2016). Patients in the SRS+WBRT group had decreased local failure compared to patients who received WBRT alone (HR, 0.27; 95% CI, 0.14 to 0.52; p < .0001) (Patil et al., 2016).

Center researchers identified 30 other studies on brain cancer that met inclusion criteria. Of the 30, seven were systematic reviews (Cage et al., 2013; Elaimy et al., 2013; Gans et al., 2013; Goyal et al., 2015; Patil et al., 2012; Y. Y. Soon, Tham, Lim, Koh, & Lu, 2014; Yang Yu Soon, Tham, Lim, Koh, & Lu, 2016); six were RCTs (Aoyama, Tago, & Shirato, 2015; El Gantery, Abd El Baky, El Hossieny, Mahmoud, & Youssef, 2014; El Gantery, El Baky, El Hossieny, Mahmoud, & Youssef,

2014; Lim et al., 2014; Lim et al., 2015; Sperduto et al., 2014); 14 were comparative, non-randomized studies (Adas et al., 2015; Baykara et al., 2014; Bougie, Masson-Cote, & Mathieu, 2015; Fauchon et al., 2013; Gerber et al., 2014; Hsieh et al., 2015; H. J. Kim et al., 2013; C. H. Lin et al., 2015; L. Lin et al., 2016; Patel et al., 2014; Rades et al., 2012a; Rades et al., 2012b; Skeie et al., 2012; Tian, Zhuang, & Yuan, 2013); and three were economic analyses (Kimmell, LaSota, Weil, & Marko, 2015; Vuong, Rades, Le, & Busse, 2012; Vuong, Rades, van Eck, Horstmann, & Busse, 2013).

Non-Small-Cell Lung Cancer (NSCLC)

There is some additional evidence to support the conclusion that SBRT is an effective treatment for NSCLC. The most recent systematic review concluded that use of SBRT has the possibility of improved local control and overall survival compared to historical controls (Jones et al., 2015).

Center researchers found insufficient evidence to conclude that SBRT is effective for treating *operable* NSCLC. A meta-analysis of six studies (n = 864 matched patients) found a superior three-year overall survival rate after surgery compared with SBRT (odds ratio [OR], 1.82; 95% CI, 1.38 to 2.40; p < .0001) (Zhang et al., 2014). There is one small RCT (n=22) of stereotactic ablative radiotherapy (SABR) compared to surgery in patents with operable stage I NSCLC. In this trial, six patients in the surgery group died compared to one patient in the SABR group. The estimated overall survival percentage at three years was 95% (95% CI, 85% to 100%) in the SABR group compared with 79% (95% CI, 64% to 97%) in the surgery group (HR, 0.14; 95% CI, 0.017 to 1.190; log-rank p = .04) (J. Y. Chang et al., 2015). Another article on the same RCT found that global health-related quality of life and indirect costs were significantly more favorable and less expensive with SABR compared to surgery (Louie et al., 2015).

Center researchers identified 30 other studies on brain cancer that met inclusion criteria. Of the 30, three were systematic reviews (Bilal, Mahmood, Rajashanker, & Shah, 2012; Solda et al., 2013; Zheng et al., 2014); 21 were comparative studies(Chiang et al., 2016; T. Crabtree et al., 2013; T. D. Crabtree et al., 2014; Ezer et al., 2015; Hamaji et al., 2015; Kastelijn et al., 2015; Koshy, Malik, Mahmood, Husain, & Sher, 2015; Lucas et al., 2014; Matsuo et al., 2014; Mokhles et al., 2015a; Mokhles et al., 2015b; Nakagawa, Negoro, Matsuoka, Okumura, & Dodo, 2014; Nanda et al., 2015; Parashar et al., 2015; Puri et al., 2015; Robinson et al., 2013; Shaverdian, Wang, Steinberg, & Lee, 2015; Shirvani et al., 2014; Shirvani et al., 2012; van den Berg, Klinkenberg, Groen, & Widder, 2015; Varlotto et al., 2013); one was a cost-effectiveness study (Shah et al., 2013); and there were no other RCTs.

Prostate Cancer

Center researchers found insufficient evidence to indicate that SBRT is an effective treatment for prostate cancer. One systematic review of case series looked at outcomes from SBRT and included 14 studies with a total of 1472 patients (Tan, Siva, Foroudi, & Gill, 2014).

Five comparative studies were identified: one study analyzed PSA slope (Anwar et al., 2014); one examined genitourinary toxicity (J. B. Yu et al., 2014); and the other three assessed patient quality of life outcomes (Evans et al., 2015; Helou et al., 2014; Katz, Ferrer, Suarez, & Multicentric Spanish Group of Clinically Localized Prostate Cancer, 2012).

- One study (n = 75) compared SBRT to conventionally fractionated EBRT for patients with low to low-intermediate risk prostate cancer. The PSA slope for SBRT was significantly greater than conventionally fractionated EBRT ($p < .05$) at two and three years after treatment, although the PSA slopes for the two groups were similar during the first year (Anwar et al., 2014).
- SBRT was compared to intensity-modulated radiation therapy (IMRT) among a national sample of Medicare beneficiaries with prostate cancer in one study (n = 4,005). Genitourinary toxicity was significantly higher in the SBRT group compared to IMRT group at six and 24 months after treatment (15.6% vs. 12.6%; OR, 1.29; 95% CI; 1.05 to 1.53; $p = 0.009$ and 43.9% vs. 36.3%; OR, 1.38; 95% CI, 1.12 to 1.63; $p = .001$, respectively) (J. B. Yu et al., 2014).
- One study (n = 803) included a multi-institutional pooled cohort analysis of patient-reported quality of life before and after IMRT, brachytherapy, or SBRT for localized prostate cancer. In a multivariate analysis, quality of life outcomes were not significantly different between the SBRT and IMRT groups in the urinary irritation or obstruction ($p = .55$), urinary incontinence ($p = .74$), and sexual domains ($p = .57$), but SBRT was associated with a better bowel score (+6.7 points; $p < .0002$) (Evans et al., 2015).
- SABR was compared to high-dose rate brachytherapy plus hypofractionated EBRT in a study (n = 207) that investigated quality of life in patients treated for localized prostate cancer. For the percentage of patients with a minimally clinical important change, SABR had significantly better quality of life outcomes in urinary function and bother ($p < .0001$), bowel function ($p = .02$), and sexual function ($p = .04$) and bother ($p = .03$) (Helou et al., 2014).
- Another study (n=339) assessed quality of life in patients treated for clinically localized prostate cancer with SBRT or radical prostatectomy. The largest differences in quality of life occurred in the first six months after treatment. There were larger declines in the surgery group compared to SBRT in urinary and sexual quality of life, and a larger decline in SBRT compared to surgery for bowel quality of life (Katz et al., 2012).

A cost-effectiveness study analyzed SBRT compared to IMRT for low-risk prostate cancer. The incremental cost-effectiveness ratios for IMRT over robotic SBRT and non-robotic BRT were $285,000 and $591,100 per QALY gained, respectively, making both significantly above the generally accepted willingness to pay threshold (Sher, Parikh, Mays-Jackson, & Punglia, 2014).

Pancreatic Cancer

Center researchers found insufficient evidence to indicate that SBRT is an effective treatment for pancreatic cancer. In one systematic review of case series of pancreatic cancer treated with robotic radiosurgery, the authors concluded that the outcomes of SBRT were similar to the outcomes in previous studies of chemo-radiation with conventional fractionation. (Buwenge et al., 2015). A comparative study (n = 41) of SBRT and IMRT for patients with locally advanced unresectable pancreatic cancer found no significant difference in overall survival between the two therapies, although SBRT showed significantly better local disease-free survival than IMRT (p = .004) (J. C. Lin, Jen, Li, Chao, & Tsai, 2015).

Liver Cancer

Center researchers found insufficient evidence to indicate that SBRT is an effective treatment for liver cancer. Three comparative studies were found:

- One study (n = 224) compared SBRT to radiofrequency ablation for inoperable, nonmetastatic hepatocellular carcinoma. Overall survival rates for SBRT compared to radiofrequency ablation were not significantly different at one year (74% vs. 70%) or two years (46% vs. 53%) (Wahl et al., 2016).
- SBRT was compared to selective internal radiotherapy in one study (n = 189) of hepatocellular carcinoma. After adjusting for confounding factors, there was no significant difference in overall survival (HR, 0.72; 95% CI, 0.49 to 1.07; p = .11) for selective internal radiotherapy compared to SBRT (Oladeru et al., 2016).
- One study (n = 365) compared SBRT combined with transcatheter arterial chemoembolization (TACE) to TACE alone for small, solitary, hypervascular hepatocellular carcinoma. Disease-free survival time of the 12 patients without previous treatments in the SBRT group was significantly higher than that of the TACE-alone group (15.7 months vs. 4.2 months; p = .03) (Honda et al., 2013).

Spinal Cancers

Center researchers found insufficient evidence to indicate that SRS is an effective treatment for spinal cancers. No studies were identified related to primary cancers of the spine. Center researchers found three studies (two comparative, one cost-effectiveness) related to spinal metastases. The two comparative studies showed a benefit of SRS for spinal metastases:

- Among patients treated for spinal metastasis from hepatocellular carcinoma, overall survival was significantly greater in those treated (n = 27) with SRS compared to those treated with conventional radiation therapy (n = 32) (7 months vs. 3 months; p = .035) (U. K. Chang, Kim, Han, & Lee, 2014).
- In a matched-pair comparative study (n = 13 pairs) of patients treated for spinal metastasis from renal cell carcinoma, patients were followed for six months, and there was significantly greater progression-free survival for those treated with SRS compared to those treated with external radiation therapy (p = .01) (Sohn et al., 2014).

The cost-effectiveness study of palliation of vertebral bone metastases showed that the incremental cost-effectiveness ratio for SBRT was $124,552 per QALY gained, which is greater than the willingness to pay threshold (H. Kim, Rajagopalan, Beriwal, Huq, & Smith, 2015).

Adrenal Cancer

Center researchers found insufficient evidence to indicate that SABR is an effective treatment for adrenal cancer. One study on adrenal cancer was included: a systematic review of non-comparative studies of SABR for the treatment of adrenal metastases with a total of 1,047 patients. No statistical analyses were performed. The authors concluded that if therapy is in the patient's interest, then surgery appears to be the best option and SABR is a reasonable alternative in inoperable patients (Gunjur, Duong, Ball, & Siva, 2014).

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Appendix A. Search Strategies

EBM Reviews: Cochrane Central Register of Controlled Trials and EBM Reviews: Cochrane Database of Systematic Reviews

2005 to December 07, 2016

Search Strategy:

1 radiosurg$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]

2 gamma knif$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]

3 (stereotac$ adj3 radiother$).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]

4 1 or 2 or 3

5 limit 4 to yr="2012 -Current"

Ovid MEDLINE®

1946 to November Week 5 2016

Search Strategy:

1 exp Radiosurgery/

2 limit 1 to (controlled clinical trial or meta analysis or practice guideline or randomized controlled trial)

3 exp Cohort Studies/

4 exp case-control studies/

5 1 and 3

6 limit 5 to yr="2002 -Current"

7 1 and 4

8 limit 7 to yr="2002 -Current"

9 limit 1 to systematic reviews

10 2 or 9

11 6 or 8 or 10

12 limit 11 to yr="2002 -Current"

13 limit 12 to english language

14 Comparative Study/

15 1 and 14

16 limit 15 to (english language and humans and yr="2002 -Current")

17 16 not 13

18 (2016$ or 2015$ or 2014$ or 2013$ or (2012$ not (201201$ or 201202$ or 201203$))).ed.

19 13 and 18

20 15 and 18

21 limit 20 to english language

22 19 or 21

23 animals/

24 humans/

25 23 not (23 and 24)

26 22 not 25

Appendix B. Excluded Studies

See attachment

About the Center for Evidence-based Policy and the Washington Health Technology Assessment program

The Center for Evidence-based Policy (Center) is recognized as a national leader in evidence-based decision making and policy design. The Center understands the needs of policymakers and supports public organizations by providing reliable information to guide decisions, maximize existing resources, improve health outcomes, and reduce unnecessary costs. The Center specializes in ensuring that diverse and relevant perspectives are considered and appropriate resources are leveraged to strategically address complex policy issues with high-quality evidence and collaboration. The Center is based at Oregon Health & Science University in Portland, Oregon.

The primary purpose of the Washington State Health Technology Assessment program is to ensure medical treatments and services paid for with state health care dollars are safe and proven to work. The primary goals are to make:

- Health care safer by relying on scientific evidence and a committee of practicing clinicians;
- Coverage decisions of state agencies more consistent;
- State-purchased health care more cost-effective by paying for medical tools and procedures that are proven to work; and
- Coverage decision processes that are more open and inclusive by sharing information, holding public meetings, and publishing decision criteria and outcomes.

Suggested citation: Mosbaek, C., King, V., & Harrod, C. (2017). *Stereotactic radiosurgery and stereotactic body radiation therapy: An evidence update.* Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

Attachment Appendix B.

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