

Health Technology Clinical Committee

Date: March 18, 2011

Time: 8:00 am – 6:30 pm

Location: SeaTac Airport Conference Center – Central Auditorium

Adopted:

DRAFT HTCC MINUTES

Members Present: Dr. Carson Odegard; Dr. Richard Phillips; Dr. Craig Blackmore; Dr. Marie Annette-Brown; Dr. Kevin Walsh; Dr. Christopher Standaert; Dr. Michelle Simon; Dr. Joann Elmore; Dr. Michael Souter; Dr. Seth Schwartz and Dr. Megan Morris.

HTCC FORMAL ACTION

1. **Call to Order:** Dr. Blackmore, Chair, called the meeting to order. Sufficient members were present to constitute a quorum.
2. **December 10th, 2010 Meeting Minutes:** Chair referred members to the draft minutes; motion to approve and second, and adopted by the committee.
 - *Action: Nine committee members approved the December 10th, 2010 meeting minutes. Two committee members abstained from voting.*
3. **Vertebroplasty, Kyphoplasty and Sacroplasty (VKS) draft Findings & Decision:** Chair referred members to the draft findings and decision and called for further discussion or objection. The VKS findings & decision was approved and adopted by the committee.
 - *Action: Nine committee members approved the VKS findings & decision document Two committee members abstained from voting.*
4. **Glucose Monitoring for Insulin Dependent Individuals under 19 years of age:** The HTCC reviewed and considered the Glucose Monitoring technology assessment report; information provided by the Administrator; state agencies; public members; and heard comments from the evidence reviewer, HTA program, an invited clinical expert, the public and agency medical directors. 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.

HTCC COMMITTEE COVERAGE DETERMINATION VOTE			
	Not covered	Covered Unconditionally	Covered Under Certain Conditions
Self-Monitoring Blood Glucose (SMGB)	0	11	0
Continuous Glucose Monitoring (CGM)	5	1	5

- ✓ *Discussion:* The Chair called for discussion on conditions related to CGM due to the majority voting for coverage. The following conditions were discussed and approved by a majority:
 - *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:
 1. Suffering from one or more severe episodes of hypoglycemia; or

Draft Version Not Officially adopted: 3-18-2011

2. Enrolled in an IRB approved trial

✓ *Action:* The committee chair directed HTA staff to prepare a Findings and Decision document on Glucose monitoring reflective of the majority vote.

5. Spinal Injections: The HTCC reviewed and considered the Spinal Injections technology assessment report; information provided by the Administrator; state agencies; public members; and heard comments from the evidence reviewer, HTA program, an invited clinical expert, the public and agency medical directors. 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.

HTCC COMMITTEE COVERAGE DETERMINATION VOTE			
	Not covered	Covered Unconditionally	Covered Under Certain Conditions
Lumbar Epidural Injection	1	0	10
Cervical-thoracic Epidural Injection	3	0	8
Nerve Block Injections	11	0	0
Sacroiliac Joint Injections	1	3	7
Intradiscal Injections	10	0	1
Facet Injections	9	1	1

✓ *Discussion:* The Chair called for discussion on conditions related to the spinal injections where the majority voted for coverage with conditions. The following conditions were discussed and approved by a majority:

- *Limitations of Coverage:* Therapeutic Epidural Injections in the lumbar or cervical-thoracic spine for chronic pain is a covered benefit when all of the following conditions are met:
 1. For treatment of radicular pain
 2. With fluoroscopic guidance or CT guidance
 3. After failure of conservative therapy
 4. No more than two without clinically meaningful improvement in pain and function, and
 5. Maximum of 3 in 6 months
- *Limitations of Coverage:* Therapeutic Sacroiliac Joint Injections for chronic pain is a covered benefit when all of the following conditions are met:
 1. With Fluoroscopic guidance or CT guidance
 2. After failure of conservative therapy, and
 3. No more than one without clinically meaningful improvement in pain and function, subject to agency review
- *Action:* The committee chair directed HTA staff to prepare a Findings and Decision document on Spinal Injections reflective of the majority vote.

SUMMARY OF HTCC MEETING TOPICS, PRESENTATION, AND DISCUSSION

Agenda Item: Welcome & Introductions

- ✓ The Health Technology Clinical Committee (HTCC) met on March 18th, 2011

Agenda Item: Meeting Open and HTA Program Update

Dr. Craig Blackmore, HTCC Chair, opened the public meeting.

- ✓ New committee members, Dr. Seth Schwartz and Dr. Joann Elmore, were introduced
- ✓ Leah Hole-Curry, HTA Program Director, provided an overview of the agenda, meeting guide and purpose, room logistics and introductions.

Agenda Item: Previous Meeting Business

December 10th, 2010 Meeting Minutes: Chair referred members to the draft minutes and called for a motion and discussion. Minutes were circulated prior to the meeting and posted.

- *Action: Nine committee members approved the December 10th, 2011 meeting minutes. Two committee members abstained from voting.*

Vertebroplasty, Kyphoplasty and Sacroplasty (VKS) Findings and Decision: Chair referred members to the draft findings and decision and called for further discussion. The draft findings and decision document was circulated prior to the meeting and posted to the website for a two week comment period. Five public comments were received, included in the meeting materials, and were reviewed and discussed.

- *Action: Nine committee members approved the Vertebroplasty, Kyphoplasty and Sacroplasty findings & decision document. Two committee members abstained from voting.*

Agenda Item: HTA Program Review

- Leah Hole-Curry, HTA Program Director, provided the HTA context for the meeting and an update on program activities including:
 - State purchasing context and budget reductions and reform efforts, medical technology is driver of increased medical costs and has quality gaps
 - HTA is designed to use reliable science and independent committee to get best information on what works, what is safe and what provides value
 - HTA outcomes include transparency; reports and articles reviewed; and coverage decisions made
 - Comparison with private industry and Medicare decisions completed
 - Program has received recent recognition from public media, clinical press, and various medical and health policy groups with either story highlights or invited presentations

Agenda Item: Glucose Monitoring for Insulin Dependent Individuals under 19 years of age Topic Review

Leah Hole-Curry, HTA Program Director, introduced the technology topic up for discussion:

- ✓ Staff provided an overview of the timeline and referred HTCC members to the included key questions and population of interest for Glucose Monitoring review.
- ✓ Staff welcomed, per HTCC request, an invited clinical expert, Dr. Patricia Fechner an Endocrinologist from Seattle Children's Hospital. Dr. Fechner completed a conflict of interest and indicated no conflicts.

Agenda Item: Public Comments

The Chair called for public comments.

- ✓ Scheduled Public Comments: Seven stakeholders scheduled time for public comments.
 - Joan Sanders, Juvenile Diabetes Research Foundation (JDRF), expressed her concerns regarding glucose monitoring (GM) being reviewed by the Health Technology Clinical Committee (HTCC).
 - Melinda Woods, parent, believes that GM is incredibly important for the well-being and quality of life of both of children suffering from diabetes.
 - Dr. Irl B. Hirsch, Washington Diabetes Care Center, expressed concern regarding the topic of glucose monitoring up for review by the committee. Stated that home blood glucose monitoring is not a cure, but it has dramatically improved both the quality of life and the risk for long-term complications in children with diabetes.
 - Dr. Catherine Pihoker, Seattle Children's Hospital, expressed concern regarding the topic of glucose monitoring up for review by the committee. Stated that intensive management is associated with better outcomes, and glucose monitoring is an integral part of management; and that guidelines recommend individualized frequency of monitoring (at least 4-6 tests/day).
 - Kathleen Schneider, RN, Seattle Children's Hospital, expressed concern regarding the topic of glucose monitoring up for review by the committee. Stated that very young children need more frequent monitoring (more susceptible to hypoglycemia, unable to express symptoms); growth, pubertal changes affect insulin needs; and adolescents are taught to check their glucose levels before driving. Furthermore, she indicated scenarios which would require more frequent monitoring (i.e., sick days; insulin pumps; menstrual periods; pregnancy; etc).
 - Dr. Lori Laffel, American Diabetes Association, expressed concern regarding the topic glucose monitoring up for review by the committee. Stated that intensive insulin therapy leads to more optimal glycemic control (measured as A1c). Type 1 diabetes is difficult to manage in youth who experience frequent, wide glycemic excursions.
 - Dr. Bruder Stapleton, Seattle Children's Hospital, expressed concern regarding the topic glucose monitoring up for review by the committee. Stated that the standard of care is intensive management for children; and that glucose monitoring is safe and effective. Patients admitted for severe acute complications are usually those who do not monitor glucose levels.
- ✓ Open Public Comments: five individuals provided comments during the open portion.
 - Faith Lumsden, Washington state citizen, expressed her concern regarding the HTA process which she felt was confusing. Urged the committee to not make a decision, but rather convene a special panel to be able to increase the amount of GM children are able to use.
 - Christine Acarregui, Bayer Healthcare, expressed her concern regarding the topic up for review by the committee. Moved by the parents trying to help their children monitor their

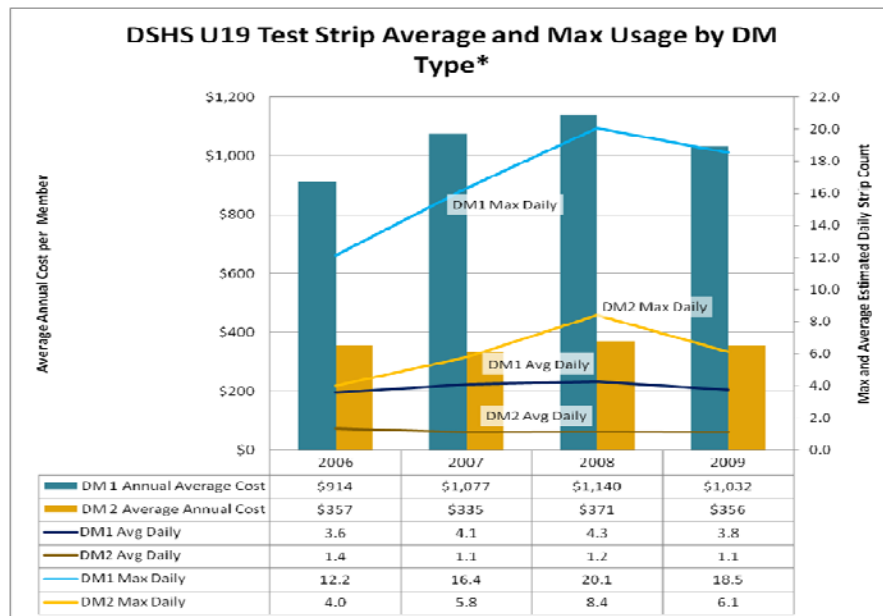
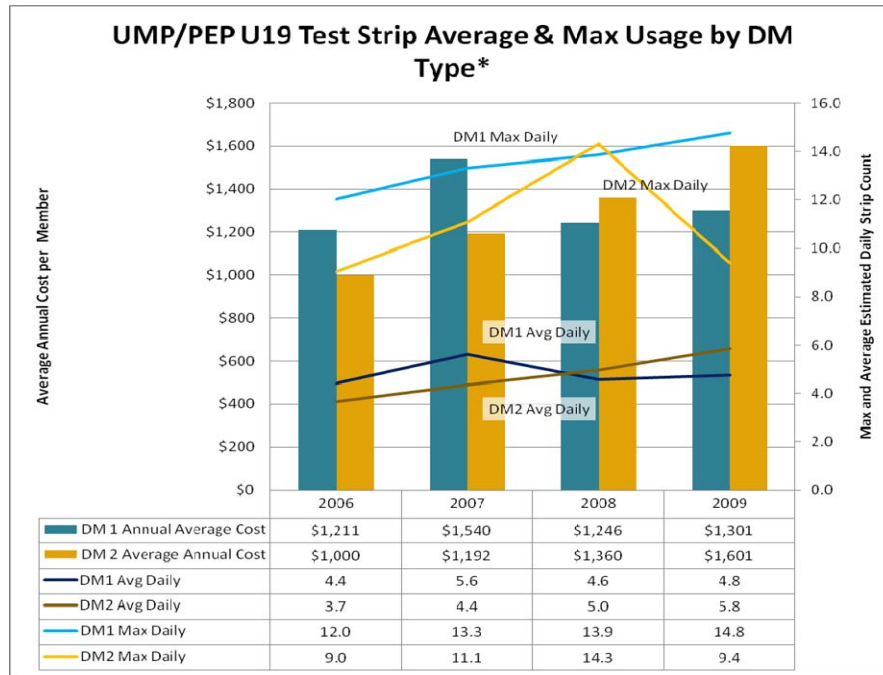
glucose levels. Encouraged the committee to provide more opportunities for children to check their insulin levels for a more quality life.

- Linnea Molder, parent, stated that intensive diabetes and insulin management has been the standard of care for the last 23 years, and should continue forward as the standard of care.
- Angela Badard, MD, Seattle Children's Hospital, expressed her concern regarding children not being able to monitor insulin levels, which is a standard of care in the United States and nationally. By limiting GM, Washington State would be moving away from the standard of care. Stated that it is unethical to put kids in studies that don't allow children to check insulin levels properly.
- Joni Campbell, Abbott Diabetes, concerned that if children can't check their insulin levels, how are they going to keep things leveled and be able to live as normal children? Concerned about taking this away. Stated that diabetes is manageable; however, but only with the right tools.

Agenda Item: Glucose Monitoring Topic – Agency Comments

Dr. Steve Hammond, Medical Director, Department of Corrections, presented the agency utilization and outcomes for Glucose Monitoring to the committee, full presentation published with meeting materials.

- ✓ Glucose Monitoring Background:
 - Routine SMBG is considered the standard of care among diabetic patients, particularly those treated with insulin. The cost of SMBG has been estimated to be about 40-50% of the total cost of care for diabetes in children.
 - Despite widespread use, there is no high-grade evidence addressing optimal frequency and strategy of SMBG. Continuous glucose monitoring (CGM) is a relatively resource-intensive technology for which even less evidence is available; CGM is not considered the standard of care in typical cases. Utilization of SMBG among pediatric patients is highly variable.
 - Guidelines, based primarily on expert opinion, typically recommend frequency of SMBG of 4 or more times/day in children with type 1 DM.
- ✓ Agency Concerns:
 - Safety (Medium) -- excessive utilization of SMBG may reflect inadequate professional clinical supervision of diabetic care and/or ineffective glycemic management.
 - Efficacy (High) -- benefits of excessive SMBG (>4-5 times/day) in terms of improved clinical outcomes are unclear.
 - Cost (High) -- the cost of SMBG is a major component of overall costs of diabetic care; unrestricted and excessive utilization carries potential for waste of limited healthcare resources (especially in the setting of inadequate professional clinical supervision and/or ineffective glycemic management).
- ✓ Agency Coverage Overview: Currently covered without quantity restrictions by UMP. Currently covered without quantity restrictions by Medicaid. Only rare coverage at L&I
 - UMP to 2006 to 2009: patients increased from 75 to 113; GM strip spending increased from \$85,000 to \$144,000. Medicaid trend from 2006 to 2009 -- patients increased from 667 to 829; GM strip spending increased from \$187,000 to \$390,000
- ✓ UMP and Medicaid Test Strip Utilization



✓ UMP / PEP U19 Diabetic Patients and Adverse Events

UMP/PEP U19 Diabetic Population	2006		2007		2008		2009	
	#	% mbrs	#	% mbrs	#	% mbrs	#	% mbrs
DM Type 1	71	83.5%	84	81.6%	118	89.4%	110	90.9%
DM Type 2	14	16.5%	19	18.4%	14	10.6%	11	9.1%
Adverse Events*								
ER visits	17	20.0%	14	13.6%	22	16.7%	15	12.4%
Critical Care	4	4.7%	2	1.9%	6	4.5%	3	2.5%
Ketoacidosis	13	15.3%	7	6.8%	5	3.8%	6	5.0%
Hyperglycemia	1	1.2%	2	1.9%	2	1.5%	4	3.3%
Diabetic coma	0	0.0%	0	0.0%	3	2.3%	2	1.7%

✓ DSHS U19 Diabetic Patients and Adverse Events

DSHS U19 Diabetic Population	2006		2007		2008		2009	
	#	% mbrs	#	% mbrs	#	% mbrs	#	% mbrs
DM Type 1	416	62.1%	452	66.6%	530	66.3%	547	65.9%
DM Type 2	241	36.1%	222	32.7%	255	31.9%	273	32.9%
Adverse Events*								
ER visits	229	34.3%	311	45.8%	352	44.0%	471	56.8%
Critical Care	42	6.3%	67	9.9%	59	7.4%	95	11.54
Ketoacidosis	75	11.2%	104	15.3%	106	13.3%	135	16.3%
Hyperglycemia	19	2.9%	33	4.9%	37	4.6%	34	4.1%
Diabetic coma	3	0.5%	2	0.3%	7	0.9%	4	0.5%

✓ AMDG Concerns:

- There is little evidence regarding optimum frequency of SMBG. There is no evidence that >5 SMBG checks per day improve clinical outcomes. There is concern that excessive use of SMBG may reflect ineffective clinical management.
- There is evidence in the Washington State UMP and Medicaid fee-for-service populations of substantial morbidity among pediatric diabetic patients reflected in use of ER and critical care services and episodes of diabetic ketoacidosis.
- Evidence for clinically significant improvement in outcomes resulting from CGM in pediatric diabetic patients is very weak

✓ AMDG Recommendations:

- Optimal management of diabetes in pediatric patients should be multimodal, guided by qualified clinicians, to include: effective glycemic management through careful attention to diet, exercise, medication, and blood glucose levels, and consideration of intensive insulin therapy as appropriate.
 - Intensive insulin therapy should be guided by regular SMBG, usually 4-5 times daily. Results of SMBG should be used appropriately to adjust diet, exercise, and insulin dosing to achieve appropriate glycemic control
- Coverage of unrestricted quantities of SMBG test strips for all cases is not justified; cover with condition of up to 5 tests/day. Coverage of >5 tests/day should require case review and justification as medically necessary.
 - Could be made available as exception to rule in Medicaid, and consider requiring specialty consultation.
- CGM should not be a covered benefit by Washington State purchased health plans (however, it could be provided in the setting of IRB-approved clinical trials).

Agenda Item: Evidence Review Presentation

Spectrum Research presented an overview of their evidence report on Glucose Monitoring, full presentation in meeting materials.

- ✓ Diabetes mellitus (DM) is a serious chronic condition for which there is no definitive cure. DM is categorized into 3 major types, based on etiology:
 - **Type 1 (T1DM):** is an autoimmune disorder that destroys pancreatic beta cells which make insulin. It is the most common form in person's ≤ 18 years old. Insulin therapy is required.
 - **Type 2 (T2DM):** Is most common in adults and is caused by insulin resistance, disordered and inadequate insulin release and excessive glucose production by the liver. Diet, exercise and oral

- medications may be effective in the first years; however, it is progressive and insulin therapy may eventually be required.
- **Gestational (GDM):** defined as glucose intolerance with pregnancy onset/first recognition of pregnancy.
- ✓ Background – Complications: Chronic complications are strongly related to DM duration and glycemic control (T1 and T2DM). Diabetic ketoacidosis (DKA): severe hyperglycemia; leading cause of hospitalizations in children with T1DM nationally; can lead to coma, death. Hypoglycemia: 3 X more common in children (vs. adults), may be difficult to detect (unawareness); can damage brain, lead to seizures, coma, death.
 - ✓ Background – DM duration is associated with chronic complications, thus, person's ≤ 18 years old may have the most to gain from maintaining good glycemic control yet have some of the greatest challenges in achieving and maintaining it.
 - Goal: Achieve/maintain glucose and A1C levels as close to normal as possible while minimizing episodes of severe hypoglycemia.
 - Intensive management with tight control has become standard of care. Self-monitoring plays an integral part since it provides data for decision making; assists in identifying and preventing hypoglycemia; provides "peace of mind" to care givers; and/or influences activities and quality of life.
 - ✓ Self-monitoring of blood glucose (SMBG) is intermittent monitoring. First FDA approval was in 1975. Capillary blood drop placed on reagent-impregnated paper strips; monitor reads and provides "snap shot" of blood glucose levels. Recommended for use at least 4 times per day; individualized.
 - ✓ Real-time Continuous Glucose Monitor (CGM) – FDA approval (7-17 years): Guardian and MiniMed Paradigm REAL-Time devices (later used w/pumps). Subcutaneously placed, enzyme-embedded sensor samples interstitial fluid glucose every 1-20 minutes. Trend information; alarms for high and low levels.
 - ✓ Primary Outcomes (based on available literature):
 - Efficacy and Effectiveness
 - Mean A1C, Achieving, maintaining target A1C levels
 - ADA goals: <6 years old 7.5% -8.5%; age 6-12 <8.0%; adolescents <7.5%
 - Clinically meaningful change 0.5%
 - Hypoglycemia, hyperglycemia, ketoacidosis
 - Microvascular complications
 - Quality of life
 - Safety
 - Device-related, Morbidity, Mortality
 - ✓ Literature Search: 240 unique potentially relevant citations. Final number of included study reports = 49 and 3 FDA SSED; multiple studies contributed information to several key questions. No full economic studies were found.
 - Primary evidence – efficacy and effectiveness
 - SMBG: 1RCT (DCCT) and 2 associated observational follow-up studies (EDIC) provide indirect evidence; 1 large registry study and 7 cross-sectional studies
 - CGM: 4 RCTS; JDRF trials' associated additional analyses; Data not uniformly available for those ≤ 18 years old
 - ✓ Key Question 1: Efficacy and Effectiveness of SMBG –
 - 1 RCT (LoE II) - Diabetes Complications and Control Trial (DCCT); N = 195 ages 13-17 years; 7.4 yrs f/u
 - SMBG ≥ 4 /day *as part* of comprehensive, intensive care (insulin dose adjustment, diet, exercise) vs. SMBG or urine testing 1/day (insulin 1-2 injections/day; no daily changes of insulin or diet)
 - Provides indirect evidence on efficacy of SMBG
 - Primary prevention (PP) cohort (n = 125); participants with no retinopathy or nephropathy
 - Secondary intervention (SI) cohort (n = 70, 1-15 years); participants with mild to moderate non-proliferative retinopathy.

- Epidemiology of Diabetes Interventions and Complications (EDIC) - 2 reports (LoE II).
 - Follow-up of DCCT participants 4 and 10 years after DCCT end;
 - Original IT group encouraged to continue regimens
 - Original CT group offered instruction on intensive therapy
- N =175 (91% of surviving DCCT adolescents) enrolled; 80% follow-up at year 10.
- Testing ≥ 4/day at 4 years: 24% IT, 29% CT and at 10 years and 64.5% IT 38.9% CT (means not provided)

✓ Key Question 1: Effectiveness of SMBG – EDIC results summary:

	Intensive	Conventional	Effect size
Mean A1c (%)			
Year 4	8.38 ± 1.7	8.45 ± 1.6	NS
Year 10	8.2 ± 2.1	8.2 ± 1.3	NS
Severe Hypoglycemia			
Year 4	51/100 p-y	57/100 p-y	RR 0.9, p = 0.749
Retinopathy Progression			
Year 4	7.1%	25.4%	77% (39, 92) p = 0.004
Year 10*	50.9%	53.4%	10% (-104, 60) p = 0.8395

- Severe non-proliferative diabetic retinopathy (NPDR) or worse and proliferative retinopathy:
 - Year 4: Lower NPDR for IT 1.4% vs. CT 14.5%, p = 0.005; 1.4% IT vs. 8.7% for proliferative
 - Year 10: no significant differences between groups
 - NS differences: macular edema, laser therapy at both times
- Nephropathy (in those without microalbuminuria or albuminuria at DCCT baseline or close; page 95 of report).
 - Year 4: IT group rates were less, but NS; no one on dialysis or with renal transplant
 - Year 10 rates were similar
- ✓ Summary and Overall Strength of Evidence for Key Question 1
 - **Efficacy of SMBG (1 RCT) – SoE is low**
 - Indirect evidence from DCCT: SMBG ≥ 4/day as part of intensive, tight control program:
 - Short term (6-12 months): Lower A1C and daily blood glucose;
 - Longer (mean 7.4 years): sustained lower A1C, daily blood glucose; retinopathy and microalbuminuria risk reduction and; faster nerve conduction velocities
 - Higher rate of hypoglycemic events with intensive treatment
 - **Effectiveness (Observational) SMBG–SoE low**
 - EDIC -2 follow-up reports 4 and 10 years post DCCT:
 - 4 years: No differences in mean A1c between groups; IT group- lower rates of retinopathy progression, lower but NS difference in microalbuminuria or albuminuria prevalence
 - 10 years: No differences in mean A1C, retinopathy progression or microalbuminuria or albuminuria
- ✓ Key Question 2: Efficacy by frequency or mode –
 - **SMBG**: DCCT results (indirect evidence, ≥ 4/day)
 - **Continuous Glucose Monitoring (CGM)**

- 5 reports from 4 RCTs of real-time CGM; bulk of evidence comes from two RCTs. Limited data; stratified by age in 2 studies. One RCT compared CGM/pump vs. SMBG/MDI.
 - CGM (+ SMBG for calibration and decision making) versus SMBG alone
 - Participants educated on data use for management decisions
- ✓ Key Question 2: Efficacy of CGM (+SMBG) vs. SMBG alone --- Participants achieving A1c targets:

A1C levels (26 weeks)	CGM	SMBG	Effect Size
JDRF 2008 (n = 114)			
<7.0%	27% (15)	12% (7)	RD 15%; p = 0.01
<7.0% with no severe hypoglycemic events	25% (14)	10% (6)	RD 15%; p = 0.02
≥ 10% relative ↓	29% (16)	12% (7)	RD 17%; p = 0.04
≥ 0.5% absolute ↓	54% (30)	31% (18)	RD 23%; p = 0.009
Hirsch 2008 (n = 40)	% NR	% NR	P = 0.052

- ✓ Key Question 2: Efficacy of CGM (+SMBG) vs. SMBG alone:
- Hypoglycemia – JDRF 2008 (N = 114)
 - ≥ 1 severe event: CGM 4 (7%), SMBG 6 (10%)
 - Rates of severe hypoglycemia: p = 0.06
 - CGM 17.9/100,000 p-y; SMBG 24.4/100,000 p-y
 - Min/day ≤ 50 mg/dl: CGM 10, SMBG 13; p = 0.50
 - Min/day ≤ 70 mg/dl: CGM 47, SMBG 59; p = 0.29
 - Hyperglycemia – JDRF 2008 (N = 114)
 - Min/day ≥ 180 mg/dl: CGM 643, SMBG 635; p = 0.58
 - Min/day ≥ 250 mg/dl: CGM 242, SMBG 268; p = 0.18
 - Quality of Life (26 weeks) -- Combined populations of JDRF 2008 (>7.0% A1C at baseline) and JDRF 2009 (<7.0% A1C).
 - Participants and parents completed diabetes-specific and general assessments of QOL
 - Measures: Hypoglycemia Fear Survey subscale (HFS), Pediatric Quality of Life Inventory (PDLQL) generic and diabetes specific editions; Problem areas in Diabetes (PAID; parents only completed).
 - No differences by treatment in mean values for any measure for either participants or parents.
- ✓ Summary and Overall Strength of Evidence for Key Question 2 is low.
- JDRF 2008 (N =114) and Hirsch 2008 (n = 40):
 - Short term (26 weeks): No differences in mean A1C; JDRF – CGM participants twice as likely to achieve A1C targets
 - JDRF: Lower rate of hypoglycemic events with CGM (but NS); % of participants achieving targets w/o such events significantly greater for CGM
 - Longer term: no studies found
 - Combined JDRF 2008 and 2009 data
 - No differences in quality of life measures at 26 weeks for either participants or parents
- ✓ Effectiveness of CGM (+SMBG): Frequency of Use -- Extension studies JDRF 2008 and sub-analysis of JDRF 2009. Observational studies (LoE II and III)
- JDRF 2008 extension studies
 - Original CGM cohort (n = 80): Lower mean A1C (maintained by 12 months) and larger percentage of participants meeting targets with use ≥ 6 days/week
 - Original SMBG cohort offered CGM (with less intensive training; n = 47): no consistent pattern of improvement in A1C or for meeting target levels based on use. Lower hypoglycemia rates reported following 6 month CGM use (p not reported).

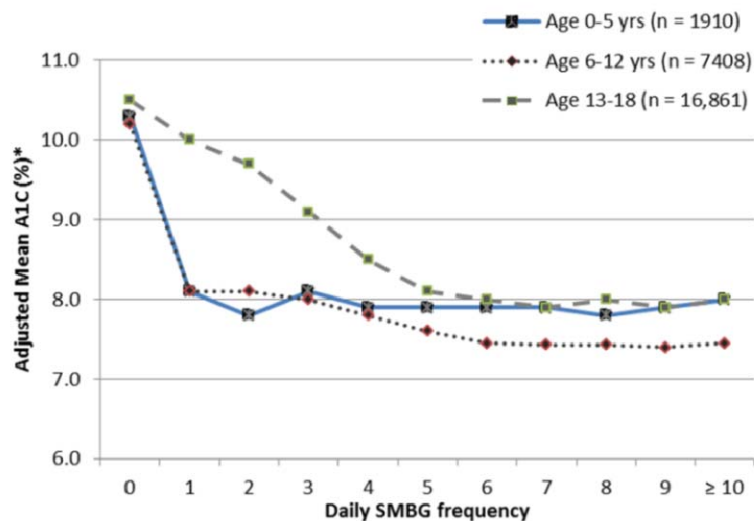
- JDRF 2009 subanalysis of those with baseline $\leq 7.0\%$ A1C: mean change in A1C of -0.72% with ≥ 6 days/week
- ✓ Effectiveness – Frequency of SMBG: 6 cross-sectional studies (LoE III).
 - N ranged from 89-2,743; 5 report statistically significant *associations* between number of SMBG per day and lower A1C in multivariate analyses. Testing at least 4 - 5 times per day.
 - Hypoglycemia and DKA (Ziegler):

	Hypoglycemic events	Diabetic Ketoacidosis events
SMBG 0-4/day	13-20 events/100 p-years	6-12 events/100 person-years (except for 1SMBG/day)
SMBG ≥ 5/day	20-37 events/100 p-years	4-6 events/100 person-years

- ✓ Summary and overall strength of evidence for key question 2 -- Frequency:
 - **Effectiveness CGM Frequency – SoE low**
 - JDRF 2008 extensions. Original CGM cohort: use ≥ 6 days/week appears to have maintained lower A1C and more met age appropriate targets. Original SMBG cohort provided with CMG: no consistent pattern of benefit with frequency of use
 - **Effectiveness SMBG Frequency – SoE low**
 - One large registry, six additional cross-sectional studies. SMBG 4-5 times per day associated with lower mean A1C. Causality cannot be inferred
- ✓ Key Question 3 – Safety:
 - SMBG: No data for current devices
 - CMG: (7 RCTs, 7 observational, 3 FDA SSED). No mortality in ≤ 18 year olds reported. Insertion site problems: Redness/itching (16%-45%); dry skin (21%); mild, moderate skin changes (14% each); irritation, bruising or pain (0-53%). Sensor/Device concerns: alarm interferes with daily routine (38%); alarm irritating (38%-50%); sensor too bulky (22%-75%); sensor pulled out (10%-13%). Many studies had small sample sizes.
- ✓ Overall strength of Data = Moderate.
 - CGM: RCTs, observational studies, SSED. Primary concerns reported: Insertion site problems, alarm related. No deaths in age group or major adverse events reported.
 - SMBG: No studies on current devices. Older reports: sore finger, difficulty obtaining samples.
- ✓ Key Question 4 – Differential Outcomes for subpopulations:
 - CGM – JDRF 2008 RCT; Participants 8-14 years old and those 15-24 years old had similar results with regard to mean A1C, hypoglycemia.
 - SMBG: Zeigler (LoE III) N = 26,723. Association between SMBG frequency and average improvement in A1C varied by age and insulin regimen.

	0-5 years (n = 1989)	6-12 years (n = 7568)	> 12 years (n = 17,166)
Mean A1C	7.59% \pm 1.34	7.61 \pm 1.32	8.46 \pm 1.85
SMBG frequency	6.0/day \pm 1.9	5.3/day \pm 1.8	4.4/day \pm 1.4
	CT (n = 5016)	MDI (n = 18,565)	CSII (n = 3142)
Mean A1C	7.64% \pm 1.67	8.24% \pm 1.75	8.01% \pm 16.0
SMBG frequency	5.3/day \pm 1.8	4.7/day \pm 1.5	5.3/day \pm 1.8

- ✓ General trend for the relationship between frequency of SMBG and adjusted mean A1c by age group (estimated by Ziegler):



- ✓ Overall Strength of Evidence for Key Question 4 = Low
 - **CGM:** 1 RCT; 8-14 year olds and 15-24 year olds had similar patterns for most results
 - **SMBG:** Registry study
 - Age: For 13-18 year olds, greater average improvement in A1C for each additional SMBG up to 5 per day. In 0-5 and 6-12 year olds, less improvement for each additional SMBG beyond the first.
 - Insulin Regimen: CSII: tests up to 10 times per day closest to targets.
- ✓ **KQ #5: Economic – no evidence, no full studies**
- ✓ Observations and Implications:
 - Diabetes management in children and adolescents presents a number of challenges and influences quality of life for the child and care givers.
 - As DM duration contributes to development of complications, this younger age group may have the most to gain from good control.
 - Self-monitoring is viewed as a critical component of management.
 - Studies did not provide specifics regarding how data from self-monitoring (SMBG or CGM) are used to influence decisions on insulin dose/regimens, diet or exercise; thus it is not possible describe the independent influence of monitoring on outcomes.
 - Adherence to monitoring and taking appropriate action based on the data are necessary to effect outcomes.
 - SMBG is part of CGM use protocol. CGM's role for pediatric use is not yet defined in the literature. No long term studies in this population were found.

Agenda Item: HTCC Glucose Monitoring Discussion and Findings

Dr. Blackmore, Committee Chair, led a discussion of the evidence related to the safety, efficacy, and cost-effectiveness of Glucose Monitoring beginning with identification of key factors and health outcomes, and then a discussion of what evidence existed on those factors.

1. Evidence availability and technology features

The evidence based technology assessment report indicates:

- 1.1 Diabetes mellitus or diabetes is a serious chronic disease characterized by elevation of blood glucose. The predominated form of diabetes in children is from an autoimmune disorder that destroys the pancreatic cells where insulin is made. There is no cure; insulin injections are required and the primary goals for treatment of youth with insulin requiring diabetes are to maintain plasma glucose and A1C levels as close to normal as possible. Diabetic ketoacidosis (very high glucose level) is the leading acute complication and can result in

morbidity and mortality. A seminal diabetes study (DCCT) results suggest that maintaining near normal levels of A1C are ideal to minimize the risk of chronic complications, but the lower the A1C puts individuals at risk of severe hypoglycemia. Children and adolescents have challenges related to varying physical capability, physiological and psycho-social changes that influence metabolism and adherence to self care behaviors.

- 1.2 Self monitoring of blood glucose has become a standard practice recommendation due to the link between good glycemic control and lower chronic complications; however, the method and optimal frequency of self-monitoring of blood glucose in patients remains controversial. Several lines of evidence have suggested an association between glucose monitoring and increased discomfort, inconvenience and worsening of depression scores with regular self-monitoring, along with a lack of clinically relevant improvement in diabetes-related outcomes in patients who self-test. On the other hand, children and adolescents can be especially at risk for some diabetes related complications. Information about the best options for glucose monitoring in diabetic persons 18 and under, including evidence of efficacy and safety and cost; and correlation of frequency (including strip frequency and continuous monitoring) to improved outcomes is needed.
- 1.3 Self-monitoring of blood glucose (SMBG) uses meters to analyze small amounts of capillary blood on reagent-coated test strips to provide immediate documentation of glycemic status. This allows one to implement strategies to address and avoid out of range glucose values. It provides only a snapshot of the blood glucose level and thus, cannot provide information on whether there is a trend toward higher or lower levels. Continuous glucose monitors (CGM) are more recent technology where a minimally-invasive device is worn to measure interstitial fluid glucose concentration via sensors which have been inserted subcutaneously. These devices take samples every 1-20 minutes over the time that the device is worn. CGM is not approved for insulin dosing decisions, so individuals using CGM must still conduct SMBG several times a day.
- 1.4 Evidence included in the technology assessment review was obtained through a structured, systematic search of the medical literature; economic studies; and clinical guidelines. 240 potentially relevant studies were identified; 49 were included; no economic studies found. The evidence is indirect because SMGB is not separately studied. Primary evidence for SMBG is 1 randomized control trial (DCCT) and 2 associated observational follow up (EDIC); 1 larger registry study and 7 cross-sectional studies. For CGM, 4 RCTs and JDRF's analysis were included, though data is not uniformly available for 18 and under.
- 1.5 The evidence based technology assessment report identified six expert treatment guidelines and no National Coverage decision (NCD) policy addressing children.
- 1.6 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. Evidence about the technology's safety

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is safe. Summary of committee considerations follows.

- 2.1 The evidence based technology assessment report indicates that the strength of evidence of safety is moderate based on number and quality of studies. SGBM and CGM have no major adverse events or deaths. (*Adverse events from severe high and low glucose are described in efficacy*).
- 2.2 The evidence based technology assessment report indicates that the primary issues for SGBM are from older studies that reported sore fingers and difficulty obtaining samples.
- 2.3 The evidence based technology assessment report indicates that for CGM, primary issues from small RCT and observational studies included skin irritation (0%- 53%); sensor dislodging (10% - 13%); alarms interfering with daily routine (38%) and irritation with alarms

(38% - 50%). The primary safety issue with CGMs are false alerts and missed alerts (false negatives); rates varied across blood glucose thresholds and devices – false negatives rates for hypoglycemia (below threshold) ranged from 14% to 75% and false negative rates for hyperglycemia (above threshold) ranged from 5% to 37%).

3. Evidence about the technology's efficacy and effectiveness

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is effective. Summary of committee considerations follows.

- 3.1 Efficacy of SMBG – the evidence based technology assessment report indicated that no studies evaluated current methods of SMBG testing alone or as an independent component of diabetes management. The Diabetes Complications and Control Trial (DCCT-1994) is the primary study of 195 patients aged 13 to 17 providing indirect evidence regarding the efficacy of SMBG as part of a package of comprehensive, intensive diabetes care, which included SMBG four or more times per day and education on how to use the information to adjust insulin, diet and exercise compared with the then standard of care (urine or SMBG once/day, only periodic insulin adjustment).
 - Mean A1c levels 8.06% for intensive care arm vs. 9.7% for conventional arm; a 61% risk reduction in sustained at least three step retinopathy in intensive arm; no difference in nephropathy; no difference in ketoacidosis (18% vs. 20%); and a threefold higher risk of hypoglycemia resulting in coma/seizure in intensive care arm.
- 3.2 Effectiveness of SMBG – the evidence based technology assessment report indicated indirect evidence on the effectiveness of SMBG is based on the Epidemiology of Diabetes Interventions and Complications (EDIC-2001) the observational follow-up to the DCCT at four and ten years with 175 patients. All participants in the conventional treatment arm were offered instruction in the use of intensive therapy and intensive treatment group patients were encouraged to continue such treatment. No significant differences between the groups identified except related to retinopathy at 4yr.
 - Mean A1c levels 8.38% for intensive arm vs. 8.45% in conventional at 4yr; and 8.2% for both groups at 10yr;
 - Retinopathy progression worse in 7% of intensive arm vs. 25% in conventional at 4yr and 51% for intensive arm vs. 53% in conventional at 10yr;
 - Severe hypoglycemia; macular edema; and nephropathy had no significant differences
- 3.3 Efficacy and effectiveness by frequency or mode of test -- there were no clinical trials that directly evaluated the efficacy of SMBG frequency. Indirect evidence from the DCCT provides information with respect to frequency in that the intensive group was instructed to test at least four times per day compared with the conventional care groups once per day (see above). The bulk of the evidence on efficacy of mode of self-monitoring comes from comparisons with continuous glucose monitors (CGM).
- 3.4 CGM used with SMBG (for calibration and verification per FDA recommendations) was compared with SMBG alone; three RCTs form primary basis; overall *Strength of Evidence is low*. Data from one JDRF 2008 report on CGM (result stratified by age (n = 114, 8-14 year olds)) and one smaller Hirsch RCT (n = 40, 12-18 year olds) are primary studies. Another JDRF (2009) study has few outcomes stratified by age. In the JDRF studies, 84% of both CGM and SMBG groups used insulin pumps (which did not communicate with the CGM) and 100% of patients in the Hirsch study used pumps integrated with the CGM device in the CGM arm only. Different in population and study design preclude pooling of data.
 - Mean differences in HbA1C levels were not clinically or statistically significant in short term.
 - No study reported significant differences in episodes of hypoglycemia for CGM vs. SMBG.

- 2 RCTs reporting on hyperglycemia reported no significant differences for CGM vs. SMBG.
- Results on the effect of CGM vs. SMBG on medication or nutritional management conflicted: 2 studies reported significant differences in insulin doses where one study reported no change in insulin doses.
- There are currently no long-term comparative studies on these devices for evaluation of benefits, complications or diabetes-related co-morbidities on those ≤ 18 years old.

4. Special Populations

- 4.1 The evidence based technology assessment report reported one RCT and one large registry study directly assessed differential outcomes for either CGM or SMBG by age subpopulations. The overall strength of evidence is low.
- 4.2 The evidence based technology assessment report included one RCT comparing CGM with SMBG in patients 8-14 years old and those 15-24 years old - each had similar results with regard to A1C and achieving targets for CGM and SMBG with no evidence of differential efficacy by age was demonstrated.
- 4.3 The evidence based technology assessment report reported that there is limited evidence for differential effect of frequency of SMBG testing by age from one large registry study.
 - For 13-18 year olds an average improvement in A1C of $0.3\% \pm 0.011$ for each additional SMBG was reported. This appears to apply up to tests five per day.
 - In contrast, for ages 0-5 and 6-12, beyond one test per day, improvement in A1C was much less and averaged $0.04\% \pm 0.018$ and $0.12\% \pm 0.010$ respectively beyond one SMBG per day.

5. Evidence about the technology's value and cost-effectiveness

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.

- 5.1 The evidence based technology assessment report indicated that no evidence is available to assess the cost effectiveness of SMBG or CMG in persons with diabetes ≤ 18 years old who require insulin. No full economic studies which focused on the cost-effectiveness of CGM or the frequency of SMBG were found.

6. Evidence on Medicare Decision and Expert guidelines

Committee reviewed and discussed the expert guidelines as identified and reported in the technology assessment report.

- 6.1 Centers for Medicare and Medicaid Services (CMS) – no NCD policy addressing children.
 - For adults, to be eligible for coverage of home blood glucose monitors and related accessories and supplies, the patient (or patient's care-giver) must meet all the following criteria:
 - Diagnosed with diabetes that is being treated by a physician
 - Glucose monitor and related supplies ordered by the treating physician with documentation of medical necessity for the prescribed frequency of testing
 - Successfully completed training or is scheduled to begin training in the use of these items
 - Capable of using the test results to assure appropriate glycemic control
 - Device is designed for home use
 - Supplies covered: Up to 100 test strips and lancets every month for beneficiaries who are insulin dependent and every 3 months for those who are non-insulin dependent, and one lancet device every 6 months for both indications.

6.2 Guidelines – the evidence based technology assessment report identified six guidelines though a search of the *National Guideline Clearinghouse*.

- American Diabetes Association (ADA), 2010 – Frequency of self-monitored blood glucose (SMBG): SMBG in general has been extensively reviewed by the ADA and is recommended for patients of all ages with type 1 diabetes. The 2010 report did not specifically address frequency for children; however, in a statement published in 2005 by the ADA entitled Care of Children and Adolescents with Type 1 Diabetes it is recommended that SMBG be performed at least four times daily. *Continuous glucose monitoring (CGM)*: CGM in conjunction with intensive insulin regimens can be a useful tool to lower A1c in selected adults (age ≥ 25 years) with type 1 diabetes. Although the evidence for A1c lowering is less strong in children, teens, and younger adults, CGM may be helpful in these groups. Success correlates with adherence to ongoing use of the device. CGM may be a supplemental tool to SMBG in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes. *Glycemic goals*: consider age when setting glycemic goals in children and adolescents with type 1 diabetes, with less stringent goals for younger children.
- Diabetes Coalition of California, California Diabetes Program, 2008 – this guideline addresses adults, children and adolescents with type 1 and type 2 diabetes mellitus. *SMBG testing*: typically test at least 4x / daily. *Lab exams*: A1c should be checked 1-2 times year if stable, quarterly if treatment changes or if not meeting goals. Target goal < 7.0% or < 1% above lab norms. For children, modify as necessary to prevent significant hypoglycemia. Furthermore, microalbuminuria should be checked beginning with puberty once the duration of diabetes is > 5 years unless proteinuria has been documented. *Self-care behaviors*: as appropriate for child’s developmental stage.
- International Society for Pediatric and Adolescent Diabetes (ISPAD), 2009 – In summary, SMBG is an essential tool in the optimal management of childhood and adolescent diabetes and, when financially possible, should be made available for all children with diabetes. The cost of BG monitoring is very expensive and in many countries the cost relative to the cost of living may make this technology unavailable. *Frequency of SMBG*: SMBG should be prescribed at a frequency to optimize each child’s diabetes control, usually 4-6 times a day, because frequency of SMBG correlates with glycemic control. *CGM*: CGM devices are becoming available that may particularly benefit those with hypoglycemic unawareness, as the devices will alarm when glucose is below a specified range or with rapid rate of fall of glucose. *Glycemic goals*: the target A1c for all child age-groups is recommended to be < 7.5%. Every child should have a minimum of one measurement of A1c per year. Ideally, there should be four to six measurements per year in younger children and three to four measurements per year in older children.
- National Institute for Health and Clinical Excellence (NICE), 2004 -- *SMBG*: who are trying to optimize their glycemic control and/or have intercurrent illness should be encouraged to measure their blood glucose levels more than four times per day. Should be encouraged to perform frequent blood glucose monitoring as part of a continuing package of care that includes dietary management, continued education and regular contact with their diabetes care team. *CGM*: who have persistent problems with hypoglycemia awareness or repeated hypoglycemia or hyperglycemia should be offered CGM systems. *Glycemic goals*: should be encouraged to use blood glucose measurements for short-term monitoring of glycemic control. The target for long-term glycemic control is an A1c level of less than 7.5% without frequent disabling hypoglycemia and the child’s care package should be designed to attempt to achieve this.
- American Association of Clinical Endocrinologists (AACE), 2010 – Personal CGM is recommended for patients with type 1 DM and following characteristics: hypoglycemic unawareness or frequent hypoglycemia; A1c over target, or with excess glycemic variability; requiring A1c lowering without increased hypoglycemia; during preconception or pregnancy. Personal CGM use is recommended for children and adolescents with type 1

DM who have achieved A1c levels less than 7.0%; youth with type 1 DM who have A1c levels of 7.0% or higher and are able to use the device on a near-daily basis. The following patients might be good candidates for personal CGM, and a trial of 2 to 4 weeks is recommended: youth who frequently monitor their blood glucose levels; committed families of young children (< 8 years old), especially if the patient is having problems with hypoglycemia.

- o British Society of Pediatric Endocrinology, 2009 – *Proven clinical indication*: to lower A1c, when this remains above the individual’s target despite optimized use of intensive insulin regimens. *Potential clinical indications – Diagnostic*: suspected nocturnal hypoglycemia and/or early morning hyperglycemia; suspected unrecognized hypoglycemia; A1c above individualized target despite intensified insulin therapy apparently optimized with self-monitoring; persistent disabling hypoglycemia despite conversion from MDI to CSII. *Potential clinical indications – Therapeutic*: further optimization of pump therapy regimens when A1c cannot be consistently lowered below 7.5%; protection against recurrent disabling hypoglycemia, and for those with hypoglycemia unawareness or debilitating fear of hypoglycemia.

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 Glucose Monitoring has been collected and summarized.

- 1.1. The evidence review summarized the evidence on the safety and efficacy of SMBG and CGM in individuals with insulin dependent diabetes, 18 years of age or under. SMBG plays an important role in the key treatment goal to managing diabetes; maintenance of good glycemic control without increase in the frequency of hypoglycemic events; there is direct evidence that optimizing glucose levels decreases both short and long term diabetes related complications; and managing glucose levels requires self checking.
- 1.2. Current best evidence is available primarily from 1 randomized control trial (DCCT) and 2 associated observational follow up (EDIC); 1 larger registry study and 7 cross-sectional studies. For CGM, 4 RCTs and JDRF’s analysis were included.
- 1.3. Self monitoring of blood glucose is a standard practice recommendation due to the link between good glycemic control and lower chronic complications; however the evidence about SMBG optimal frequency is unknown and additional methods (CGM) benefit is unclear.

2. Is it safe?

The committee concludes that the comprehensive evidence indicates that SMBG is safer than alternatives (limited or no self testing); and CGM is unproven to be equally or more safe to SMBG. Key factors to the committee’s conclusion included:

- 2.1. The committee unanimously agreed that moderate quality evidence demonstrates SMBG is more safe than conventional treatment (including limited or no self testing): minor skin irritations related to testing site were only reported harm; major morbidity or mortality is not anticipated with this intervention, and none was reported in the literature.
- 2.2. A majority of the committee agreed that the safety of adding CGM is unproven when compared to conventional treatment or SMBG. Low quality evidence included documented adverse events of skin irritation in up to 53% of patients; sensor dislodging (10% - 13%) and alarms interfering with daily routine (38%) and irritation with alarms (38% - 50%). Additionally, the primary safety issue with CGMs are false alerts and missed alerts (false negatives)

because a primary potential benefit of CGM is the ability to lower events of hypoglycemia; rates varied across blood glucose thresholds and devices – false negatives rates for hypoglycemia (below threshold) ranged from 14% to 75% and false negative rates for hyperglycemia (above threshold) ranged from 5% to 37%.

3. Is it effective?

The committee concludes that the comprehensive evidence shows that SMBG is a more effective treatment than alternatives (limited or no self testing); and CGM is unproven to be equally or more effective treatment than SMBG. Key factors to the committee's conclusion included:

- 3.1. The committee unanimously agreed that sufficient evidence exists to conclude that SMBG is a more effective treatment compared to conventional treatments or CGM.
- 3.2. The committee agreed that insufficient evidence exists to conclude that CGM is an effective treatment.

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.

- 4.1. The evidence based technology assessment report compared CGM with SMBG and indicated one RCT. Patients 8-14 years old and those 15-24 years old had similar results with regard to A1C and achieving targets for CGM and SMBG with no evidence of differential efficacy by age was demonstrated, based on one RCT.
- 4.2. The evidence based technology assessment report reported that the SMBG frequency evidence is from one large registry study. There is limited evidence for differential effectiveness for frequency of SMBG by age. For 13-18 year olds an average improvement in A1C of $0.3\% \pm 0.011$ for each additional SMBG was reported. This appears to apply up to tests five per day. In contrast, for ages 0-5 and 6-12, beyond one test per day, improvement in A1C was much less and averaged $0.04\% \pm 0.018$ and $0.12\% \pm 0.010$ respectively beyond one SMBG per day.

5. Is it cost-effective?

The committee concludes that the SMBG is more cost effective than conventional treatments and CGM. CGM is unproven to be cost effective; agreeing with the comprehensive evidence review that no evidence based conclusions about cost effectiveness can be drawn.

- 5.1. The evidence report adequately summarized the very low quality evidence on cost which helped the committee conclude that CGM is not a cost effective treatment.

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 Glucose Monitoring demonstrates that there is sufficient evidence to cover self-monitoring of blood glucose (SMBG) for insulin dependent individuals under the age of 19. The committee agreed that there is sufficient evidence on continuous glucose monitoring for insulin dependent individuals under the age of 19 to cover with conditions. 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 to cover self-monitoring of blood glucose (SMBG). Based on these findings, the committee voted to cover with conditions continuous glucose monitoring (CGM).

Glucose Monitoring Coverage Vote

The clinical committee utilized their decision tool to first gauge committee judgment on the status of the evidence in the three primary areas of safety, efficacy, and cost.

Self-monitoring of blood glucose (SMBG) --

Is there sufficient evidence under some or all situations that self-monitoring of blood glucose for insulin dependent individuals under the age of 19 is:

	Unproven (no)	Equivalent (yes)	Less (yes)	More (yes)
Effective	0	0	0	11
Safe	0	0	0	11
Cost-effective Overall	3	0	0	8

Continuous Glucose Monitoring (CGM) --

Is there sufficient evidence under some or all situations that continuous glucose monitoring for insulin dependent individuals under the age of 19 is:

	Unproven (no)	Equivalent (yes)	Less (yes)	More (yes)
Effective	11	0	0	0
Safe	9	2	0	0
Cost-effective Overall	11	0	0	0

Glucose Monitoring Coverage Vote: Based on the evidence provided and the information and comments presented, the committee moved to a vote on coverage.

HTCC COMMITTEE COVERAGE DETERMINATION			
	Not covered	Covered Unconditionally	Covered Under Certain Conditions
Self-monitoring of blood glucose (SMBG)	0	11	0
Continuous Glucose Monitoring (CGM)	5	1	5

- Action: The committee vice-chair directed HTA staff to prepare a Findings and Decision document on glucose monitoring reflective of the majority vote for final approval at the next public meeting.
- ✓ *Limitations of Coverage:* Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, Continuous Glucose Monitoring (CGM) is a covered benefit for diabetes mellitus (DM) patients under 19 using insulin when all of the following conditions are met:
 - Suffering from one or more severe episodes of hypoglycemia
 - Or involved in an IRB approved trial

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The committee discussed Clinical guidelines and Medicare decision, and their coverage determinations are consistent with the clinical guidelines and Medicare decision. The committee found that the evidence review summarized the most recent, relevant evidence and assessed its quality along with addressing key questions relevant to the committee's statutory criteria including evidence on safety, efficacy, effectiveness and cost that were addressed or transparent in clinical guidelines.

Agenda Item: Spinal Injections Topic Review

Leah Hole-Curry, HTA Program Director, introduced the technology topic up for discussion:

- ✓ Staff provided an overview of the timeline and referred HTCC members to the included key questions and population of interest for the Spinal Injections review.
- ✓ Staff welcomed, per HTCC request, an invited clinical expert, Dr. Craig Hartrick, clinical anesthesiologist and researcher at William Beaumont Hospital in Michigan. Dr. Hartrick prepared a COI with no conflicts listed, other than his professional affiliation as Editor in Chief of Pain Practice.

Agenda Item: Public Comments

The Chair called for public comments.

- ✓ Scheduled Public Comments: Eighteen stakeholder groups requested scheduled time for public comments.
 - The following clinicians provided comment in support of spinal injections based on their clinical experience and observation and belief that spinal injections are effective and safe. The commenters believe that spinal injections increase function; reduce need for other interventions that are riskier; and/or are accepted by medical and specialty societies. Restrictions on spinal injections could lead to more unnecessary spinal surgeries. Believe that evidence report inclusion/exclusion criteria are inappropriate and authors have conflict. Issues with overuse are not related to the treatment but are caused by increased providers without adequate training or controls or not using imaging guidance. No additional clinical evidence was cited.
 - Paul Dreyfuss, MD; Ray Baker, MD; Way Yin, MD; Nikolia Bogduk, MD; Richard Rosenquist, MD; John Carrino, MD; Carolyn Marquardt, MD; Andrew J. Cole, MD; Jason Attaman, DO; Jeffrey Roh, MD; Llewellyn N. Packia Raj, MD; Irene Young, MD; Yung J. Lee, DO; Michael Hatzakis, Jr., MD; Alison Stout, DO and Trent L. Tredway, MD collectively.
 - Elin Bjorling, American Pain Foundation (APF), provided comment in support of spinal injections based on concern that Washington State has a one size fits all decision making approach, which disregards the individual needs of the pain population. No additional clinical evidence was cited.
 - Deryk Lamb, patient, provided comment in support of spinal injections based on his personal experience with failed back surgery syndrome; spinal injections are part of his regimen and concerned those barriers to finding pain care will decrease his quality of life and that Washington state patients deserve appropriate pain management care access, including spinal injections.
- ✓ Open Public Comments: Six individuals provided comments during the open portion.
 - The following clinicians provided comment in support of spinal injections based on their clinical experience and observation and belief that spinal injections are effective, increase function; reduce need for other interventions that are riskier; and/or are accepted by medical and specialty societies. Several commenters did acknowledge that overutilization occurs and appropriate candidates need to be identified. No additional clinical evidence was cited.
 - Carlos Moravek, MD, Franciscan Medical Group
 - Zachary Abbott, MD, Olympia clinician
 - Brett Quave, MD, Medical Director at Watersedge Yakima Memorial
 - Doug Burns, MD, Evergreen hospital

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- Andrew Engle, MD
- Mary Winkler, Washington state employee and patient receiving spinal injections provided comment in support of spinal injection based on her personal experience. Believes that while spinal injects are unpleasant, they have allowed her to remain working and does not believe other options are available.

Agenda Item: Spinal Injections – Agency Data

Josh Morse, Department of Labor & Industries, presented to the committee the agency utilization and outcomes for Spinal Injections. Full PowerPoint slides in meeting materials.

- ✓ Spinal Injections Background: Up to 75% of the population will have an episode of pain at some point in life. Spinal injections may be used to treat and/or isolate the source of back or neck pain, typically when: it has become chronic (more than 3 or 6 months w/o relief), and Conservative measures have failed to provide relief.
- ✓ Agency Concerns:
 - Safety Concerns (Low): Spinal injections are invasive techniques to infiltrate tissues in the vicinity of major nerves of the CNS with anesthetic or anti-inflammatory agents. Though risk is reportedly low, infection and allergic reactions are safety concerns.
 - Efficacy Concerns (Medium): The efficacy of spinal injections is rated medium. It is unclear what effect spinal injections may have on long term improvement in back pain and function.
 - Cost Concerns (Medium): Back pain is common among Washington insured. The cost-effectiveness of spinal injections is unknown, yet the volume of utilization significant and rising.
- ✓ Coverage Overview: Currently covered by UMP, Medicaid and Labor and Industries. UMP and Medicaid have no limits and prior authorization is not required.
- ✓ LNI Coverage has limits - Overview:
 - Epidural injections may be authorized when there is evidence of nerve root irritation or radiculopathy. The intent is to identify the involved nerve root(s), or to reduce inflammation of same.
 - Epidural steroid injections are limited to 3 in the first 30 days. No more than 6 per episode.
 - Must be under fluoroscopic guidance, or performed in an accredited facility.
 - Facet joint injections are covered when provided by qualified specialists in orthopedics, neurology, and anesthesia. Injections must be performed in an accredited hospital under radiographic control. Not more than four facet injection procedures are authorized in any one patient.
- ✓ Utilization Cost for all agencies (*average per patient per year; **average per patient per 4 years):

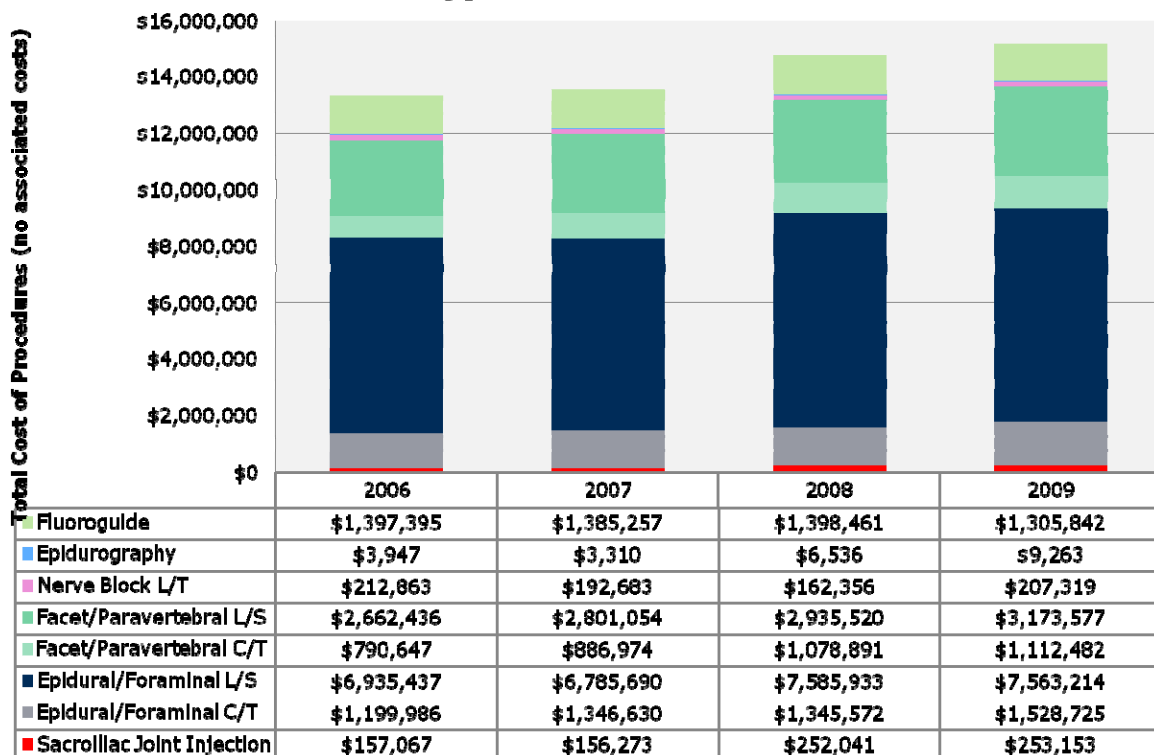
	2006	2007	2008	2009	4 Year Total
Procedures	34,298	33,994	39,667	44,128	152,087
Patients	9,010	9,072	10,025	11,078	36,846
Avg Cost L&I per patient	\$2231	\$2353	\$2336	\$2161	\$2268*
Avg Cost DSHS per patient	\$517	\$503	\$520	\$523	\$648**
Avg Cost UMP per patient	\$1429	\$1418	\$1507	\$1491	\$1925**

✓ Utilization Costs for all agencies:

Direct Costs (millions)	2006	2007	2008	2009	4 Year Total
Total	\$13.1	\$13.3	\$14.5	\$14.9	\$55.7
L&I	\$10.4	\$10.4	\$10.8	\$10.6	\$42.1
DSHS	\$1.3	\$1.3	\$1.5	\$1.8	\$6.0
UMP	\$1.4	\$1.56	\$2.2	\$2.4	\$7.7

✓ Agency Utilization – combined agency costs of Spinal Injections by Type, 2006 – 2009:

Combined Agency Costs of Spinal Injections by Type, 2006-2009



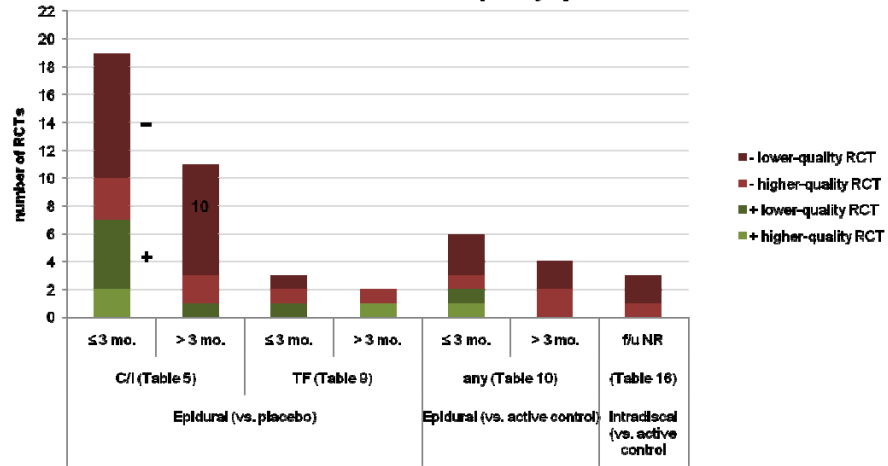
- ✓ Increase in Utilization: Spinal injection costs increased in all agencies between 6 and 16% from 2008 to 2009. 6.1% increase in L&I despite 15% decrease in claim volume. 76% of utilization, \$42 million, is in workers' compensation.
- ✓ Summary: The best evidence from the Spectrum report shows only 'mixed results' for the most common spinal injections for back pain with sciatica or radiculopathy including: Lumbar caudal or interlaminar epidural steroid injections and transforaminal steroid injections.
 - A large body of evidence appears to show no benefit from a variety of different injection techniques for a number of conditions including: Spinal stenosis; low back pain without sciatica or radiculopathy; failed back surgery syndrome; facet joint pain and discogenic back pain.
- ✓ AMDG Considerations:
 - Is there a category of injections where coverage with conditions makes sense?
 - If there is, should it be only for monoradiculopathies and/or for multiple levels? Single root injections for monoradiculopathies? Injections for multiple roots (bilateral or multiple levels)?
 - Is there any evidence for coverage of any injection for chronic, non-radicular back pain?
- ✓ Agency Recommendations based on the available evidence and agency experience: Coverage with conditions for of spinal injections.
 - Limitations of coverage: 1 Epidural steroid injection for radiculopathy when:
 - Conservative treatment has failed
 - There is documentation of clinical evidence of sciatica or radiculopathy (e.g., altered sensation, inability to heel-toe walk)
 - Additional injections may be covered the first injection is demonstrated to provide relief (pain and function) for the expected duration
 - Non-coverage for therapeutic facet joint injections; therapeutic intradiscal injections or any injections for chronic, non-radicular back pain

Agenda Item: Evidence Review Presentation

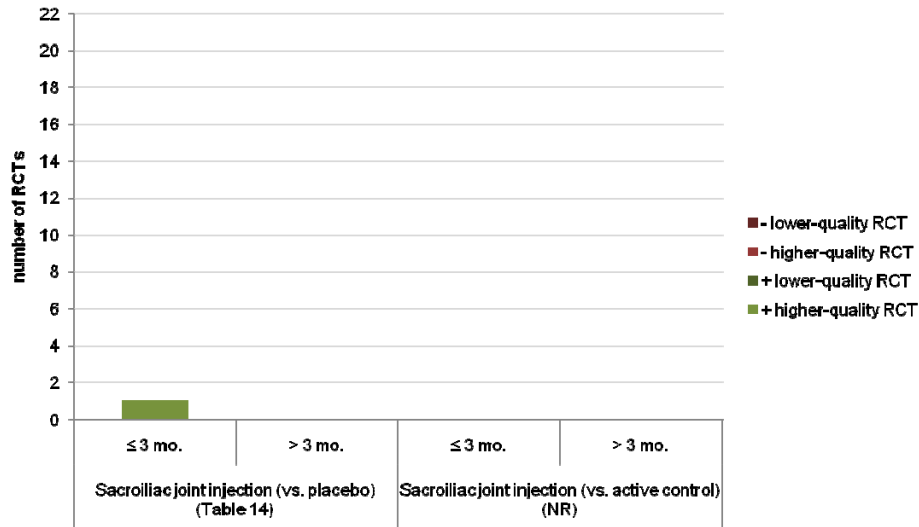
Spectrum Research presented an overview of their evidence report on Spinal Injections. A full set of slides and information is included in the meeting materials.

- ✓ Spinal Injections Background: typically considered only after failure of conservative treatment. Injection of anti-inflammatory agent (steroid) and local anesthetic into spine or surrounding nerves and joints. Injection often monitored with fluoroscopic or CT visualization. Deliver treatment directly to pain source (theoretical advantage).
- ✓ Literature Search: For key questions 1-3 (n = 1 SR; n = 22 RCTs); (n = 7 cohort studies) and (n = 24 case series). For key question 4 (n = 2 economic analyses).
- ✓ Key Question 1 inclusions: RCTs published in English. For lumbar injections: RCTs ≤ 2008 as reported in the APS / Chou et al (2009) SR and RCTs ≥ 2008. Exclusions: unreported diagnosis; < 75% of patients had excluded diagnosis; study type other than RCT and/or abstracts, letters and editorials. Key Question 1 outcomes = pain relief; physical function; opioid use; return to work; quality of life and patient satisfaction. Comparisons include 5 variables = injection type; injection approach (epidural only); diagnosis; control intervention (placebo, active control); and study quality.
- ✓ Lumbar Spinal Injections:

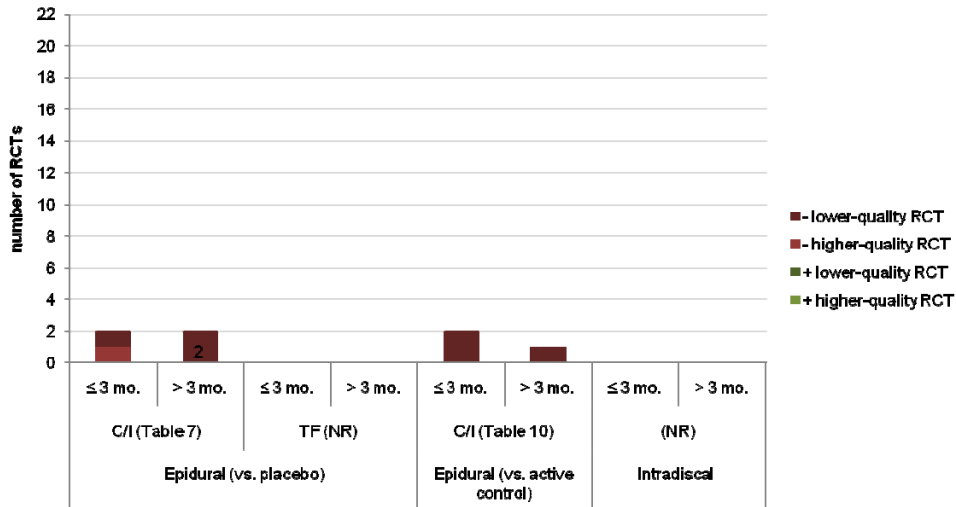
Sciatica/radiculopathy: pain



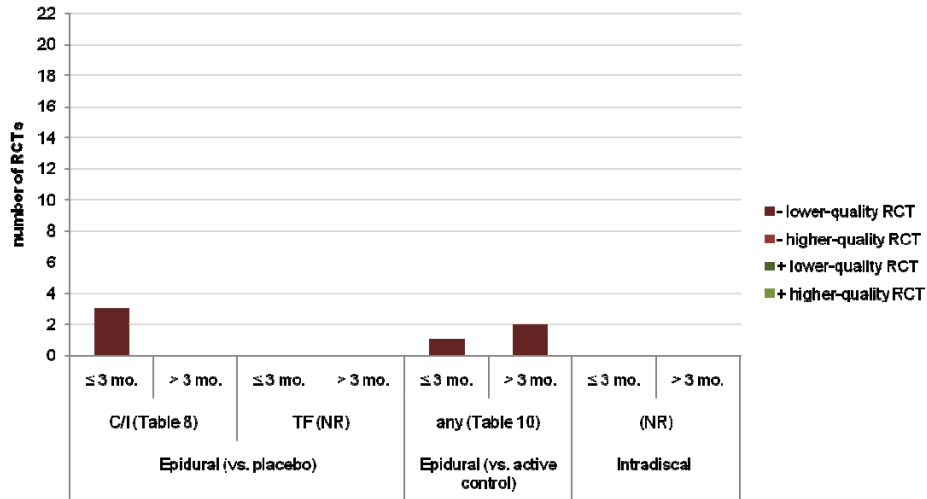
Lumbar pain from SI joint: pain



Spinal stenosis: pain & function

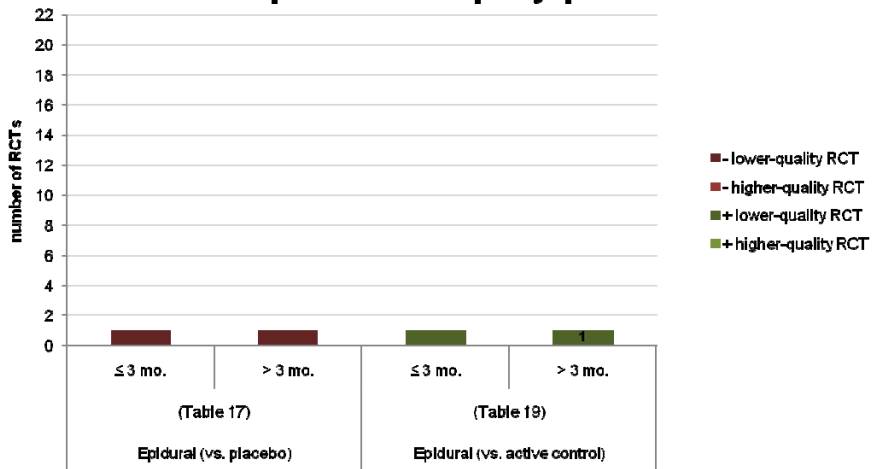


FBSS: pain & function

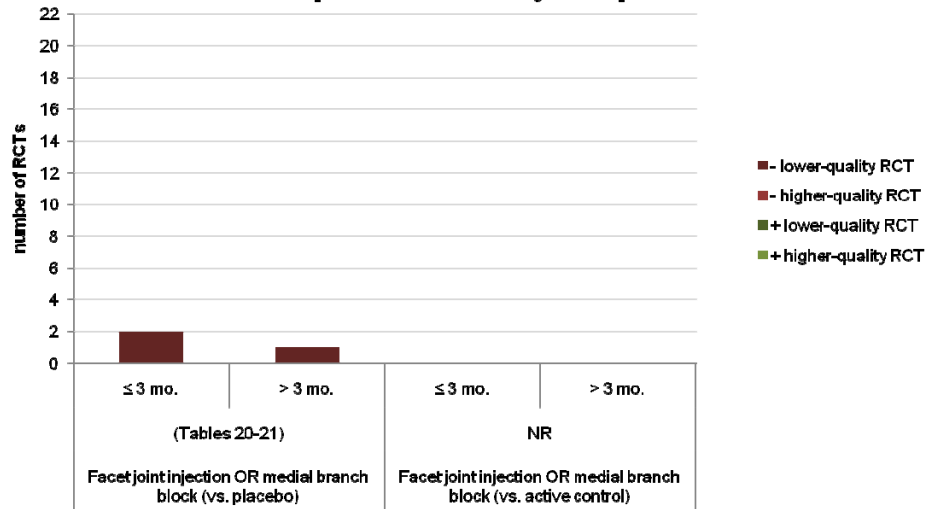


✓ Cervical Spinal Injections

Neck pain + radiculopathy: pain



Cervical pain from facet joint: pain



- ✓ Key Question 2 inclusions: RCTs + APS SR as included in Key Question 1. Case series designed to report complications (n ≥ 100). Exclusions = case reports.
- ✓ Major complications: lumbar spinal injections (SoE = High [major complications are rare])

	RCTs (APS/Chou SR + 14 RCTs)	Case series (6 studies)
Death attributed to procedure	0/1146 patients	0/10,416 injections
Paralysis	0/1146 patients	0/10,416 injections
Dural puncture	1/1556 injections or patients	1/10,416 injections
Subarachnoid puncture	1/1556 injections or patients	1/10,416 injections
Angina pectoris	1/1556 injections or patients	0/10,416 injections

- ✓ Key Question 2 – major complications: cervical spinal injections (SoE = High [major complications are rare])

	RCTs (5 RCTs)	Case series (4 studies)
Death attributed to procedure	0/326 patients	0/7240 injections or patients
Paralysis	0/326 patients	0/7240 injections or patients
Dural puncture	0/710 injections or patients	2/6330 patients
Subarachnoid puncture	3/710 injections or patients	NR
Life-threatening anaphylactice reaction	NR	1/7240 injections or patients
Grand-mal seizure	NR	1/7240 injections or patients
Local hematoma	NR	1/7240 injections or patients

- ✓ Key Question 2 – minor complications. Overall rate of minor complications: 0.06% - 16.3% injections or patients (19 RCTs, 14 case series).
- ✓ Key Question 3 inclusions: comparative clinical studies (RCTs, cohort studies with concurrent controls). Exclusions = Non-clinical (e.g., technical reports); case reports; unreported diagnosis; and < 75% of patients had excluded diagnosis.
- ✓ Key Question 3 – no strong evidence of differential efficacy or safety in subpopulations based on the following characteristics: injection approach (lumbar epidural) = 8 RCTs, 2 retrospective cohort studies; diagnosis = 1 RCT, 4 retrospective cohort studies; baseline pain and dysfunction = 1 RCT, 1 prospective and 3 retrospective cohort studies; injectate characteristics = 1 RCT; sex = 3 retrospective cohort studies; age = 3 retrospective cohort studies; and imaging = 2 retrospective cohort studies.
- ✓ Economic conclusions = SoE very low (no evidence of cost effectiveness)
- ✓ Points to Consider – Efficacy:
 - On one hand: Large number of RCTs. No clear benefit of epidural steroid injections in sciatica patients. In general, no benefit of spinal injections for other types of back pain; fewer trials reporting.
 - On the other hand: Heterogeneity relating to injection types and approaches, diagnosis, control groups and study quality. Heterogeneity between control interventions makes interpretation of results somewhat challenging. Possible benefit in the following cases (1 study each): LBP from

the SI joint treated with SI joint blocks. Cervical radiculopathy treated with epidural steroid injections.

- ✓ Points to Consider – Safety:
 - On one hand: major complications are rare. Minor complications are more common.
 - On the other hand: Major complications have been reported in case reports; incidence unclear. Minor complications are generally transient in nature.
- ✓ Point to Consider – Cost Effectiveness:
 - Based on 2 RCTs: epidural versus placebo injections in patients with LBP + sciatica. Higher quality study showed no cost benefit. Short-term cost benefit (3 – 4 weeks) in lower quality study not sustained. Other injection types not evaluated.

Agenda Item: HTCC Spinal Injections Discussion and Findings

C. Craig Blackmore, Committee Chair, led a discussion of the evidence related to the safety, efficacy, and cost-effectiveness of Spinal Injections beginning with identification of key factors and health outcomes, and then a discussion of what evidence existed on those factors.

1. Evidence availability and technology features

- 1.1 The evidence based technology assessment report estimates 75% of the population has an episode of back pain at some point in their life. While most acute back pain resolves within a few months, surveys report that approximately 5% of the population has chronic back pain, with significant social and economic impacts. Those affected can have disabling symptoms that can dramatically affect their quality of life and ability to perform a variety of activities. The source and pathology of chronic spinal pain is not well understood but has been attributed degenerative disc disease (DDD), herniated nucleus pulposus (HNP) (or herniated/slipped disc), spinal stenosis, radiculopathy, failed back surgery syndrome (FBSS), facet joint syndrome, among other causes.
- 1.2 The evidence based technology assessment report indicates treatment for chronic back pain typically begins with the identification (or ruling out) of underlying cause of pain and beginning conventional medical management (CMM). CMM may include conservative/ non-invasive interventions such as physical therapy and rehabilitation, pharmaceutical pain management, psychological therapy and coping skills, exercise, education, antidepressants, cognitive behavioral therapy and supported self-management, spinal manipulation, electrical stimulation, injections outside the spine, implanted devices, acupuncture/acupressure, and modified work.
- 1.3 The evidence based technology assessment report indicates that a small percentage of non-responsive patients may proceed to invasive therapies, including spinal injections. Spinal injections are not curative but are intended to provide pain relief and functional improvement for up to several months. Spinal injections involve the injection of an anti-inflammatory agent such as a steroid and/or an anesthetic into the spine or space around the spinal nerves and joints. One of the theoretical advantages of spinal injections is that they deliver medication directly to the site thought to be the source of pain. Types of spinal injection include epidural, facet joint, intradiscal, and sacroiliac joint injections. Spinal injections can be used for diagnostic and therapeutic purposes. According to one study examining Medicare claims of lumbosacral injections, the number of epidural steroidal injections increased 271% and the number of facet injections increased 231% from 1994 to 2001. A similar study found that lumbar facet joint injections/diagnostic blocks increased 161% from 2002 to 2006.
- 1.4 Despite dramatic growth in procedures, evidence about the impact of spinal injections on important patient oriented outcomes related to impact on pain, physical function, opioid use; return to work; quality of life; patient satisfaction; avoidance of more invasive surgery; expected duration of impact; need for repeat procedures; frequency and type of harms; as well as clinical impacts of multilevel or procedure differences and any evidence about

differential effect based on different patient, social or provider characteristics; different injection types; and impact of cost is needed.

- 1.5 The evidence based technology assessment report indicates that the Spinal injection evidence base is extensive: initial search resulted in over 2,700 potential citations; and based on evaluation against inclusion criteria, 1 Systematic review; 22 RCTs, 24 Observational Studies and two economic studies were included.
- Evidence was identified on five injection types: epidural (lumbar and cervical); facet joint; sacroiliac; intradiscal injections and medial branch blocks.
 - Key strengths of the overall body of evidence are a large evidence base including randomized clinical trials.
 - Limitations in the overall body of evidence: despite well validated measures to evaluate treatment outcomes, evidence is limited by the variety of different measures or non-validated measures used; most studies were limited by a focus on one outcome - impact on short term pain; studies not including a placebo arm are limited when measuring subjective improvement in pain; many studies were limited by short duration (3 month or less) for treatment of a chronic condition; there remains uncertainty over clinically meaningful improvement for pain and function; and the variety of injection methods and types.

2. Evidence about the technology's safety

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is safe. Summary of committee considerations follows.

- 2.1 Major Complications: the evidence based technology assessment report indicated that major reported complications of spinal injection include dural puncture; subarachnoid puncture and angina pectoris, though rates are rare.
- There were no cases of death or paralysis related to the procedure in the included studies, though death unrelated to the procedure was reported in 10 of 1146 patients in the RCTs, and there have been case reports of death and paralysis in the published literature.
 - For dural or subarachnoid punctures, or other life threatening complications, the reported rates ranged from 3 in 710 injections to 5 in 7240 (cervical) and 1 in 1556 injections to 1 in 10,416 injections for lumbar.
 - Vascular Puncture: the evidence based technology assessment report indicated the mean incidence of intravascular puncture following fluoroscopically guided lumbar spinal injections was 10.18% (range, 1.9–22%) as reported in five case series designed to assess its incidence.
- 2.2 Minor Complications: the evidence based technology assessment report indicated that minor complications are more common but are generally transient in nature. The overall minor complication rate ranged from 0.06% to 16.3% of injections or patients in 19 RCTs and 14 case series, and complications included: pain at the injection site, increased radicular pain/numbness/weakness, nerve root irritation, superficial infections, sympathetic blockade, facial flushing, vasovagal reactions/fainting, headache, gastric complaints, dizziness, pruritis, irregular periods, and insomnia.
- 2.3 Radiation Exposure to the Physician: the evidence based technology assessment report indicated the with proper protective measures, total radiation exposure was within normal limits following a mean of 923 procedures (range, 100 – 1819) with an average length of radiation exposure of 9.8 seconds/procedure (range, 4.9 – 15.2) in all five case series we identified.
- The evidence based technology assessment report reported that approximately 50% of four million interventional medical procedures per year are performed under

fluoroscopic guidance. Fluoroscopy for spinal injections is routinely used to ensure correct needle placement, accurate delivery of the injectate, and avoidance of complications. Incorrect needle placement during spinal injections without the use of fluoroscopy has been reported by various studies in 12.5% to 38.3% of patients. A C-arm fluoroscope allows the X-ray tube to be moved around the prone patient and an image intensifier enhances the image, making it easier to interpret. Although studies have shown that radiation exposure to physicians using fluoroscopy for spinal injections is within safety limits, other methods, including ultrasound and CT, are being investigated as non-radioactive or lower radioactive methods of needle guidance.

3. Evidence about the technology's efficacy and effectiveness

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is effective. Summary of committee considerations follows.

3.1 Discussion focused on the following categories of injections: lumbar epidural; cervical/thoracic epidural; facet joint injection; sacroiliac joint injection; medial branch block; and intradiscal injection. Further differentiation was not focused on as the evidence based technology report indicated low to very low overall strength of evidence of different impact. The low level of evidence reported no consistent differential impact based on the approach to administering the injection; the diagnosis, pre-injection pain intensity; type of steroid, gender, age or other patient characteristics.

3.2 **Epidural Steroid Injections for lumbar or low back pain with sciatica or radiculopathy** was highly studied and reported on; however, the overall strength of evidence is low based on the individual trial limitations and the inconsistency in results. Low back pain with sciatica or radiculopathy *the evidence is mixed* about the impact of spinal injection on pain (and in some studies function); with some studies showing a inferior results compared to placebo or other interventions and some studies showing a positive result.

- When compared to placebo for caudal or interlaminar: *In the short-term* (≤ 3 months) there was mixed evidence based on data from twenty RCTs, seventeen of which were included in the Chou/APS SR (seven were considered to be higher-quality trials). Seven of seventeen studies included in the SR reported no benefit or inferior results while another seven reported positive results and three reported unclear results. Three LoE IIb RCTs published after the SR were added here, two reported on pain (both negative) and three on function (two negative and one positive) at three months. *In the long-term* (> 3 months) there was mixed evidence based on data from twelve RCTs, nine of which were included in the Chou/APS SR. Seven of nine studies included in the SR reported no benefit or inferior results while positive results were reported by one study and another reported mixed results. Regarding the more recent RCTs included here, two reported on pain (both negative at twelve months, although one was positive at six months) and three on function (mixed results, one positive, one mixed, and one negative). (SoE = Low)
- When compared to placebo for transforaminal: mixed evidence based on data from four RCTs, two of which were included in the Chou/APS SR and considered to be higher-quality and two of which were more recent LoE IIb studies. In terms of pain relief, the data suggest a benefit at two weeks (one study), mixed results at one month (two studies- one positive and one negative), and no benefit by 3 months. No benefit in function was reported at three months by two studies. Long-term data were mixed as reported by two higher-quality RCTs, both of which were reported in the Chou/APS SR, with one study reported positive results while the other showed no benefit. When compared to intramuscular injections, transforaminal steroid injections were superior to intramuscular injections in terms of pain relief at one month based on data from one LoE IIb RCT. (SoE = Low)

- 3.3 **Epidural Steroid Injections for lumbar or low back pain without sciatica or radiculopathy** was also studied and reported on, and the overall strength of evidence is low to moderate based on the individual trial limitations and indication studied. The evidence indicates *no benefit* of spinal injections compared either to placebo, physical therapy, trigger point injection, discectomy or dry needling.
- Low back pain (without sciatica or radiculopathy) compared to placebo showed no benefit based on data from three RCTs, one of which was included in the Chou/APS SR and considered to be a lower-quality trial. The two more recent RCTs rated IIb also reported no benefit in pain, function, or opioid use at three months or in employment at twelve months. (SoE = Moderate)
 - Spinal Stenosis compared to placebo: *In the short-term* (24 hours – 3 months), there was no benefit based on data from four RCTs, three of which was included in the Chou/APS SR; one was considered to be a higher-quality trial. Three of four studies reported no benefit; one study reported improved walking distance at one week. In a recent RCT, LoE IIb there was no benefit in pain, function, or opioid use at three months. (SoE = moderate). *In the long-term* (13 – 30 months), there was no benefit based on data from two RCTs as reported in the Chou/APS SR. (SoE = Low)
 - Failed back surgery syndrome compared to placebo: no benefit based on data from three RCTs, two of which were included in the Chou/APS SR and considered to be lower-quality trials. In the one recent LoE IIb RCT, there was no benefit in pain, function, or opioid use at three months. (SoE = Moderate)
 - Spinal Stenosis compared to physical therapy or control: no benefit in terms of pain, function, or quality of life at three and six months based on data from one LoE IIb RCT. (SoE = Very Low)
- 3.4 **Epidural Steroid Injections for cervical pain** reported overall strength of evidence of very low based on small number of trials, trial limitation and inconsistent results. The evidence indicates *mixed benefit* of epidural cervical spinal injections.
- For neck pain with disc herniation and radiculitis (comparator = placebo): *no benefit* in terms of pain, function, or opioid use at both three and twelve months or on employment at twelve months based on data from one LoE IIb RCT. (SoE = Very Low)
 - Neck pain without disc herniation and radiculitis (comparator = placebo): *no benefit* in terms of pain, function, or opioid use at both three and twelve months or on employment at twelve months based on data from one LoE IIb RCT. (SoE = Very Low)
 - Neck pain with disc compression and radiculitis (comparator = intramuscular injection): epidural injections were *superior* to intramuscular injections in the posterior neck in terms of pain, analgesic use, and employment at one week and twelve months based on data from one LoE IIb RCT. (SoE = Very Low)
- 3.5 **Facet Joint Steroid Injections** overall had low strength of evidence of no benefit based on four RCTs.
- Confirmed or presumed lumbar facet joint pain compared to placebo: no benefit in the first three months based on data from two RCTs included in the Chou/APS SR, one of which was considered to be lower-quality. Although one of the studies reported a statistically meaningful benefit at six months in patient improvement following steroid injection, the rationale for this late response is not clear. (SoE = Low)
 - Non-radicular back pain and facet joint osteoarthritis compared to hyaluronic acid: no benefit in the injection of steroids versus hyaluronic acid into the facet joint at six months based on data from one higher-quality RCT included in the Chou/APS SR. (SoE = Low)
 - Confirmed cervical facet joint pain compared to placebo: no benefit in terms of the length of pain relief based on data from one LoE IIb RCT. No long-term data was reported. (SoE = Very Low)

- 3.6 Sacroiliac Joint Steroid Injections had low overall strength of evidence of benefit based on one RCT.
- For sacroiliac Joint Pain, compared to placebo: sacroiliac joint injections were superior to placebo injections based on data from one higher-quality RCT included in the Chou/APS SR. (SoE = Low)
- 3.7 Intradiscal Injections overall had moderate strength of evidence of no benefit based on seven RCTs.
- For discogenic back pain, steroid injection compared to placebo: no benefit based on data from three RCTs included in the Chou/APS SR, one of which was higher-quality. (SoE = Moderate)
 - For sciatica compared to chemotherapy: no benefit based on data from three RCTs included in the Chou/APS SR, one of which was higher-quality. (SoE = Moderate)
 - For low back pain without radiculopathy using neurolytic agent compared to placebo: intradiscal injections with methylene blue were superior to placebo injections in terms of pain, function, patient satisfaction, and analgesic use in the long-term (6-24 months) based on data from one LoE IIa RCT. (SoE = Low)
- 3.8 Medial Branch Blocks overall had low to very low strength of evidence of no benefit based on four RCTs.
- For confirmed lumbar facet joint pain compared to placebo: no benefit in terms of pain or function at both three and twelve months or on opioid use at twelve months based on data from one LoE IIb RCT. (SoE = Very Low)
 - For presumed lumbar facet joint pain compared to Sarapin: no benefit in injections with Sarapin with or without steroid based on data from one higher-quality and one lower-quality RCT included in the Chou/APS SR. (SoE = Low)
 - For confirmed cervical facet joint pain compared to placebo: no benefit in terms of pain or function at both three and twelve months or on opioid use or employment at twelve months based on data from one LoE IIb RCT. (SoE = Very Low)

4. Special Populations

- 4.1 Approach of the Epidural Steroid Injection: the evidence based technology assessment report indicated no consistent evidence from a systematic review of six RCTs and two additional RCTs published since the systematic review that one approach is more efficacious in administering lumbar epidural steroid. The results of one lower quality RCT suggest that interlaminar injections may not be as efficacious as transforaminal in patients with axial only pain from spinal stenosis. However, more study is needed to verify these findings.
- 4.2 Diagnosis: the evidence based technology assessment report indicated no consistent evidence that epidural steroid injections have differential efficacy or effectiveness among various diagnoses of the lumbar or cervical spine.
- 4.3 Pre-injection pain intensity or duration, type of steroid, sex, age, or MRI findings: the evidence based technology assessment report indicated no consistent evidence that pre-injection pain intensity or duration, type of steroid used as injectate, sex, age or pre-injection MRI findings are associated with outcome in patients receiving epidural steroid injections of the lumbar or cervical spine.

5. Evidence about the technology's value and cost-effectiveness

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.

- 5.1. The evidence based technology assessment report reported no evidence that epidural steroid injections are cost effective based on data from two economic analyses. One moderately well conducted cost utility analysis (QHES 78/100) suggested that one epidural steroid injection is a more cost effective patient management strategy than up to three injections and that cost effectiveness ratios for epidural steroid injections are too high to be considered cost effective by UK conventions. Further, the budget impact of epidural spinal injections is likely large because of high use. Poor economic data (QHES 49/100) from a second trial (Karppinen) suggested that over one year epidural steroid injections do not show cost or outcome advantages compared to saline injections, and that contained herniations may be more responsive to steroid injection than bulges or extrusions.
- 5.2. The evidence based technology assessment report reported no economic data were available for facet injections, medial branch blocks, sacroiliac joint injections, or intradiscal injections or for any type of cervical injection.
- 5.3. Washington state agency utilization and cost information indicated costs for Spinal Injections of \$55M for the past four years with a rising trend.

6. Evidence on Medicare Decision and Expert guidelines

Committee reviewed and discussed the Medicare Decision and expert guidelines as identified and reported in the technology assessment report.

- 6.1 The Centers for Medicare and Medicaid Services have no published National coverage determinations (NCD) for any spinal injections.
- 6.2 Guidelines – a search of the core sources and relevant specialty groups identified fourteen guidelines.
 - o American Pain Society (APS), 2009: For patients with nonradicular low back pain, the APS is unable to assess the benefit of epidural steroid injection, facet joint steroid injection, medial branch block, or sacroiliac joint injection based on insufficient or poor evidence. Corticosteroid facet joint injection is not recommended based on moderate evidence. Intradiscal steroid injection is not recommended for treatment of nonradicular low back pain based on good evidence. For patients with radicular low back pain, the APS found moderate evidence for short-term (through three months) benefit from epidural steroid injections based on fair evidence. A recommendation for epidural steroid injection for patients with symptomatic spinal stenosis is not offered based on insufficient or poor evidence.
 - o American Society of Interventional Pain Physicians, 2009: The recommendation for caudal epidural steroid injection in managing lumbar spinal pain with disc herniation and radiculitis or discogenic pain without disc herniation or radiculitis is 1A or 1B, indicating a strong recommendation where the benefits outweigh the risks of treatment. In addition, the recommendation for caudal epidural steroid injection for patients with post-lumbar laminectomy syndrome and spinal stenosis is 1B or 1C, also indicating a strong recommendation. The recommendation for use of cervical interlaminar epidural injection for disc herniation and radiculitis to achieve short-term relief is 1C. For patients seeking long-term relief, the recommendation is 2B (weak recommendation), indicating benefits are balanced with risks and burdens of treatment. In patients with spinal stenosis and discogenic pain without disc herniation and radiculitis the recommendation is 2C (very weak, with uncertainty in estimates of benefits, risk, and burden of treatment). The recommendation for lumbar transforaminal epidural injections is 1C. Intraarticular facet joint injections are not recommended. Cervical, thoracic, and lumbar facet joint nerve blocks are recommended to provide both short-term and long-term relief in the treatment of chronic facet joint pain (recommendation 1B or 1C).
 - o Institute for Clinical Systems Improvement (ICSI), 2009: Epidural steroid injections and facet joint injections are classified as level I (standard, first-line) therapeutic procedures, and are recommended as part of a comprehensive treatment plan that includes

pharmacologic, rehabilitative, and psychological interventions. Evidence is limited when such procedures are used alone.

- American College of Occupational and Environmental Medicine (ACOEM), 2008: Epidural glucocorticosteroid injection is recommended as a treatment option for subacute radicular pain syndromes, and as an option for second-line treatment of acute flare-ups of spinal stenosis associated with true radicular or radiculomyelopathic symptoms based on low potential harm to the patient and low costs (Evidence Rating I: insufficient evidence). Epidural glucocorticosteroid injection is not recommended to treat chronic neck pain or for dorsal spine symptoms that predominate over leg pain based on evidence that harms and cost exceed benefits to the patient (Evidence Rating C: limited evidence). The ACOEM makes no recommendation regarding the use of facet joint injection for flare-ups of neuropathic pain or chronic low back pain (Evidence Rating I: insufficient evidence). Facet joint injection is not recommended for any radicular pain syndrome, chronic non-specific axial pain, and repeat injections are not recommended for patients who failed to achieve lasting functional improvements after a prior injection for neuropathic or chronic low back pain based on evidence that treatment is ineffective or that costs or harms outweigh benefits to the patient (Evidence Rating B: moderate evidence).
- Institute for Clinical Systems Improvement (ICSI), 2008: ICSI recommends epidural steroid injection only after conservative treatment has failed and to avoid surgical intervention. ICSI finds limited evidence for the efficacy of epidural steroid injection, but indicates it may allow patients to progress with conservative treatments. Epidural steroid injection should be performed under fluoroscopy with contrast in order to prevent treatment failure.
- Work Loss Data Institute, Low back – lumbar & thoracic (acute & chronic), 2008: Epidural steroid injection and sacroiliac joint injections are recommended as part of a comprehensive treatment plan for low back pain. Specifically, epidural steroid injection is recommended to avoid surgery for severe cases with radiculopathy, but does not offer long-term functional benefit. “Series of three” epidural steroid injections, facet joint injection (multiple series, thoracic, and medical branch blocks), and intradiscal steroid injection were considered but are not recommended.
- Work Loss Data, Neck and upper back (acute & chronic), 2008: Epidural steroid injection is recommended as part of a comprehensive treatment plan for radicular pain. Specifically, epidural steroid injection is recommended to avoid surgery in severe cases with neurologic findings. Facet joint injection was considered but is not recommended.
- Work Loss Data, Pain (chronic), 2008: Epidural steroid injection is recommended as part of a comprehensive treatment plan. Facet blocks are classified as under study by the Institute and are not currently recommended.
- American Academy of Neurology, 2007: The American Academy of Neurology indicates the use of epidural steroid injections may result in a small magnitude of improvement in radicular lumbosacral pain when evaluated 2-6 weeks post-injection, but the recommendation is classified as a level C (possibly effective) due the small number of relevant studies, highly select patient population, and variation in comparison treatments in the evidence base. Epidural steroid injections are not recommended for radicular lumbosacral pain due to a lack of evidence for improvement of function, need for surgery or long-term pain relief beyond 3 months. This recommendation is classified as level B (probably ineffective based on Class I-III evidence). There was insufficient evidence to make a recommendation regarding the use of epidural steroid injections to treat cervical radicular pain.
- American College of Occupational and Environmental Medicine, 2007: The use of epidural glucocorticosteroid injection is recommended as a second-line treatment of acute spinal stenosis flare-ups, and as a treatment option for acute or subacute radicular pain syndromes lasting at least 3 weeks after treatment with NSAIDs and when pain is

- not trending towards spontaneous resolution. Both treatments are recommended based on low potential harm to the patient and low costs (Evidence Rating I: insufficient evidence). The use of facet joint injections is not recommended for acute, subacute, chronic low back pain, and radicular pain syndrome based on evidence that the treatment is ineffective or that harms and cost exceed benefits to the patient (Evidence Rating B: moderate evidence). Sacroiliac joint corticosteroid injection is recommended as an option for patients with specified known cause of sacroiliitis (Evidence Rating C: limited evidence). The use of epidural glucocorticosteroid injection is not recommended for acute, subacute, or chronic low back pain in the absence of radicular signs and symptoms (Evidence Rating C: limited evidence).
- American College of Physicians and the American Pain Society, 2007: Epidural steroid injection is an option for patients with prolapsed lumbar disc with persistent radicular symptoms who have not responded to noninvasive therapy. No specific recommendation is given for this or any other injection therapy of interest.
 - North American Spine Society (NASS), 2007: The NASS recommends nonfluoroscopically-guided interlaminar epidural steroid injection as a treatment option for short-term symptom relief in patients with neurogenic claudication or radiculopathy. A single radiographically-guided transforaminal injection may also provide short-term symptom relief for patients with radiculopathy (Grade B: fair evidence). A multiple injection regimen of radiographically-guided transforaminal epidural steroid injection or caudal injections may provide long-term symptom relief in patients with radiculopathy or neurogenic intermittent claudication, but evidence supporting this recommendation is of poor quality.
 - EuroCOST: European evidence-based guideline COST B13 Working Group on Guidelines for Chronic Low Back Pain, 2006: Epidural steroid injection, facet joint injection, and facet nerve blocks are not recommended based on a lack of evidence or conflicting evidence. Intradiscal injections are not recommended for the treatment chronic nonspecific low back pain based on evidence they are not effective (level B: moderate evidence).
 - American Association of Neurological Surgeons; Congress of Neurological Surgeons, 2005: Lumbar epidural injections and facet injections are recommended as treatment options for temporary, symptomatic relief in some patients with chronic low back pain, but epidural injections are not recommended for long-term relief of pain, based on Class III evidence (unclear clinical certainty). Facet injections are not recommended as long-term treatment for low back pain based on Class I evidence (high clinical certainty).

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 Injections has been collected and summarized.

- 1.1 The committee appreciated and agrees that chronic back pain is a serious condition that can be debilitating. Causes of chronic back pain are not well understood and current treatment aims to reduce pain and improve function. Spinal injections are advocated as an alternative treatment proposed for patients with chronic back pain who have not responded to conventional medical management. Spinal injections are an invasive procedure, compared to conventional medical management, but are less invasive than surgical interventions. Proposed benefits of spinal injections is that medication is delivered directly to the area thought to be the source of pain; and for individuals that have not responded to conventional

medical management who might otherwise consider surgery, spinal injections may be less invasive, risky, and costly.

- 1.2 The evidence based technology assessment report searched and summarized evidence on common types of spinal injections; to identify any patients most likely to benefit based on patient oriented outcomes including pain, function, long-term effects, prevention of surgery, return to work, opioid use and quality of life. Despite a robust quantity of evidence, including over 30 randomized controlled trials, the strength of evidence on Spinal Injections was overall low to moderate with results showing no benefit; and some low quality evidence showing mixed results (some trials positive, some negative) for certain injections and indications.

2. Is it safe?

The committee concludes that the comprehensive evidence indicates that Lumbar Epidural injections are equally safe to alternative treatments. Safety for Cervical Epidural injections; Medial Branch Block injections; Intradiscal injections; Facet Joint injections and Sacroiliac Joint injections are unproven. Key factors to the committee's conclusion included:

- 2.1. The committee agreed that there is insufficient evidence about the safety of most spinal injections, including cervical epidural injections, medial branch block injections, intradiscal injections, facet joint injections, and sacroiliac injections. The committee agreed that the procedures are invasive and have risk, though minor complications are most common.
- 2.2. The committee agreed that the relatively large body of evidence did not include any reports of morbidity following injections in trials, though the trials were unlikely to be powered for this rare event, and there are some case reports.
- 2.3. The committee agreed that the evidence demonstrated that major complications that can be life threatening include dural puncture; subarachnoid puncture; and pectoral angina occur, but are rare following; however trial reporting of complications was variable (some did not report on complications at all), and thus may be underreported.
 - Lumbar spinal injections had more clinical evidence reported where ranges could be identified from at least 14 RCTs (1/1556 event per injection); and 6 non-randomized studies that evaluated complications post procedure with major complications occurring at 1/10,416 injections and minor complications 5.8%.
 - The committee agreed that vascular puncture was identified as an adverse event, reported to occur about 10% (range 1.9-22%) in fluoroscopically guided lumbar injections.
- 2.4. The committee agreed that predominately minor complications are common but are generally transient in nature. The overall complication rate ranged from 0.06% to 16.3% of injections or patients and included: pain at the injection site, increased radicular pain/numbness/weakness, nerve root irritation, superficial infections, sympathetic blockade, facial flushing, vasovagal reactions.

3. Is it effective?

The committee concludes that the comprehensive evidence indicates that Lumbar Epidural injections are equally more effective than alternative treatments. Effectiveness for Cervical Epidural injections; medial branch block injections; Intradiscal injections; Facet Joint injections and Sacroiliac joint injections are unproven. Key factors to the committee's conclusion included:

- 3.1. The committee agreed that the evidence for spinal injections is generally low despite a relatively large quantity of trials, leaves many key questions about patient outcomes unanswered; but there has been a sharp rise in use (up to 271%) over the past decade.
 - Overall, the majority of randomized controlled trials *reported no benefit*.

- A subset of trials, mainly around lumbar epidural injections showed mixed results. Strengths of the body of evidence include the relatively larger number of randomized controlled trials that included comparison to placebo for efficacy questions. Limitations weakening the relatively large quantity of trials included: patient sample sizes in trials were small; reported outcomes focused on a small subset of subjective patient oriented outcomes that were not consistently reported; and the overall body of evidence shows no benefit or is inconsistent.
 - The committee agreed that several key questions remain unaddressed: a primary proposed advantage for spinal injections is the prevention of surgery; however, evidence is lacking on this outcome; and the expected duration of effect and number of repeated treatments for this chronic condition (and appropriate follow up time for trials) is a key determinate for overall effectiveness and net benefit, but is not addressed.
 - Patient oriented outcomes such as meaningful impact on function; quality of life; patient satisfaction; impact on opioid use; and return to work, were either not measured at all, or not measured or reported using consistent, validated instruments.
- 3.2. The committee agreed that epidural Steroid Injections were the most highly studied. The committee focused on evidence related to lumbar back pain (with and without radiculopathy) and then cervical/thoracic pain.
- 3.3. The committee agreed that for epidural injections for lumbar pain without radiculopathy, the evidence that injections are effective is unproven, based on low to moderate quality evidence of no benefit when compared either to placebo, physical therapy, trigger point injection, discectomy or dry needling based on eight randomized trials for various indications that showed no benefit in pain or function, nor opioid use or quality of life for those trials that measured it.
- 3.4. The committee agreed that the evidence showed that epidural injections for lumbar pain with sciatica or radiculopathy is more effective than conservative management based on seven of seventeen studies that showed benefit over placebo or comparator interventions, while acknowledging the overall evidence is low and some is mixed. The committee agreed that higher weight should be placed on more recent studies to assure that more modern techniques (guided) were used and evaluated.
- From the Chou Systematic review, seventeen total trials (seven were considered to be higher-quality trials) were identified; seven reported positive results; seven reported no benefit or negative results; and three were unclear. Three lower quality RCTs published after the SR were also included; with two reporting negative results and one reporting positive results. Regarding the more recent RCTs, two reported on pain (both negative at twelve months, although one was positive at six months) and three on function (mixed results, one positive, one mixed, and one negative).
 - Of the studies using more modern techniques including Ng, Reu, and Karpinnin reported improvement in pain (including leg pain) and ODI scores.
- 3.5. The committee agreed that the evidence of effectiveness of epidural injections for cervical pain is unproven based on low evidence of mixed benefit from three included trials. The committee agreed that higher weight should be placed on more recent studies to assure that more modern techniques were used and evaluated. For neck pain with radiculitis two studies showed no benefit in terms of pain, function, or opioid use at both three and twelve months or on employment at twelve; but one study showed superior results in pain, analgesic use, and employment at one week and twelve.
- 3.6. The committee agreed that effectiveness of facet joint injections is unproven based on low quality evidence from five studies that reported no benefit as well as three systematic reviews with mixed results where two lower quality systematic reviews reported no benefit, while one low quality systematic review reported short term benefit. The two placebo controlled studies, one of higher quality, reported no clinically significant response at three months, but a statistically significant response at six months. The committee discussed the

Spinal Injections Vote: Based on the evidence provided and the information and comments presented, the committee moved to a vote on coverage.

HTCC COMMITTEE COVERAGE DETERMINATION VOTE			
	Not covered	Covered Unconditionally	Covered Under Certain Conditions
Lumbar Epidural Injection	1	0	10
Cervical-thoracic Epidural Injection	3	0	8
Medial Branch Block Injections	11	0	0
Sacroiliac Joint Injections	1	3	7
Intradiscal Injections	10	0	1
Facet Injections	9	1	1

- *Action:* The committee chair directed HTA staff to prepare a Findings and Decision document on Spinal Injections reflective of the majority vote.
- *Limitations of Coverage:* Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, therapeutic Epidural Injections in the lumbar or cervical-thoracic spine is a covered benefit when all of the following conditions are met:
 1. For treatment of radicular pain
 2. With fluoroscopic guidance or CT guidance
 3. After failure of conservative therapy
 4. No more than two without clinically meaningful improvement in pain and function
 5. Maximum of 3 in 6 months
- *Limitations of Coverage:* Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, therapeutic Sacroiliac Joint Injections for chronic pain is a covered benefit when all of the following conditions are met:
 1. With Fluoroscopic guidance or CT guidance
 2. After failure of conservative therapy
 3. No more than one without clinically meaningful improvement in pain and function, under agency review

The committee reviewed the Clinical guidelines and Medicare decision. The Centers for Medicare and Medicaid Services have no published national coverage determinations (NCD) for any spinal injections. Therefore, the committee's coverage determinations are consistent with the clinical guidelines.

issue of whether fluoroguidance was used in the primary two trials from 1991 and 1989 as it was not reported and this is now a standard of care. The committee agreed with the evidence reviews' question about the biological rationale for the injection working at 6 months, but not at 3 months and the note that the intervention group received co-interventions (physical therapy). Due to the questions about the technique and results, the committee agreed that the evidence was insufficient (not confirmatory of no benefit) on effectiveness of facet joint injections.

- 3.7. The committee agreed that effectiveness of sacroiliac joint injections overall is unproven based on low evidence, but one small, higher quality trial showed that patients without spondyloarthropathy showed benefit at one month in improved VAS scores, which would be consistent with expectations of a peripheral joint.
- 3.8. The committee agreed that intradiscal injections overall is unproven based on moderate evidence of no benefit; the data from three RCTs included in the systematic review were most compelling (two from 2004 and one from 1992) on 316 patients showing negative results on pain and function at both two weeks and one to two years.
- 3.9. The evidence on effectiveness of medial branch blocks is unproven based on overall very low quality evidence, with one study that showed no benefit at 3, 12, or 24 months in pain scores; individuals achieving more than 50% pain relief; improvement in ODI scores; or changes in opioid use.

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.

- 4.1. The committee agreed that it would be important to know whether any sub-population, technique, patient or other characteristics impacts the effect of spinal injections. Except for the presence of radiculopathy, current studies reviewing procedure approach or patient characteristics were low quality, but generally found no benefit of spinal injections. The committee agreed with the evidence based report that there is inadequate evidence to identify characteristics that either enhance or reduce the efficacy of spinal injections such as approach of epidural steroid injection; diagnosis; or pre-injection pain intensity or duration, type of steroid, sex, age, or MRI findings.

5. Is it cost-effective?

The committee concludes that no compelling evidence exists with respect to spinal injections being cost-effective and thus the cost effectiveness of all spinal injections are unproven.

- 5.1. The committee agreed that insufficient evidence exists to conclude that epidural steroid injections are cost effective based on data from two economic analyses.
- 5.2. The committee agreed that no evidence was reported for facet injections, medial branch blocks, sacroiliac joint injections or Intradiscal injections for any type of cervical injection.

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 Injections demonstrates that there is sufficient evidence to cover with conditions the use of therapeutic Epidural injections in the lumbar or cervical-thoracic spine for chronic pain.

- The committee concluded that the current evidence on Spinal Injections demonstrates that there is sufficient evidence to cover with conditions therapeutic Sacroiliac joint injections for chronic pain.
- The committee concluded that the current evidence on Spinal Injections demonstrates that there is insufficient evidence to cover the other therapeutic spinal injections: Facet joint injections; medial branch block injections; and Intradiscal injections.

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 to cover with conditions lumbar epidural injections. Based on these findings, the committee voted to cover with conditions cervical-thoracic epidural injections. Based on these findings, the committee voted to not cover medial branch blocks. Based on these findings, the committee voted to not cover Intradiscal injections. Based on these findings, the committee voted to not cover facet injections. Based on these findings, the committee voted to cover with conditions Sacroiliac joint injections.

Spinal Injections Coverage Vote

The clinical committee utilized their decision tool to first gauge committee judgment on the status of the evidence in the three primary areas of safety, efficacy, and cost.

Spinal Injections Evidentiary Votes:

Is there sufficient evidence under some or all situations that lumbar epidural injections are:

	Unproven (no)	Equivalent (yes)	Less (yes)	More (yes)
Effective	2	0	0	9
Safe	1	8	1	1
Cost-effective	10	0	1	0

Is there sufficient evidence under some or all situations that cervical-thoracic epidural injections are:

	Unproven (no)	Equivalent (yes)	Less (yes)	More (yes)
Effective	10	1	0	0
Safe	9	1	1	0
Cost-effective	11	0	0	0

Is there sufficient evidence under some or all situations that medial branch block (cervical + lumbar) injections are:

	Unproven (no)	Equivalent (yes)	Less (yes)	More (yes)
Effective	10	1	0	0
Safe	11	0	0	0
Cost-effective	11	0	0	0

Is there sufficient evidence under some or all situations that intradiscal injections are:

	Unproven (no)	Equivalent (yes)	Less (yes)	More (yes)
Effective	11	0	0	0
Safe	11	0	0	0
Cost-effective	11	0	0	0

Is there sufficient evidence under some or all situations that facet injections are:

	Unproven (no)	Equivalent (yes)	Less (yes)	More (yes)
Effective	11	0	0	0
Safe	11	0	0	0
Cost-effective	11	0	0	0

Is there sufficient evidence under some or all situations that sacroiliac joint injections are:

	Unproven (no)	Equivalent (yes)	Less (yes)	More (yes)
Effective	9	0	0	2
Safe	11	0	0	0
Cost-effective	11	0	0	0

**Health Technology Clinical Committee
Findings and Coverage Decision**

Topic: Glucose Monitoring for Insulin Dependent Individuals Under 19 Years of Age

Meeting Date: March 18th, 2011

Final Adoption:

Number and Coverage Topic

20110318A – Glucose Monitoring for Insulin Dependent Individual Under 19 Years of Age

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

❖ **Non-Covered Indicators**

- N/A

❖ **Agency Contact Information**

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

Health Technology Background

The Glucose Monitoring topic was selected and published in December 2008 to undergo an evidence review process. The evidence based technology assessment report indicates that self-monitoring of blood glucose (SMBG) and continuous glucose monitoring (CGM) are two techniques that persons with diabetes use at home to help them maintain blood glucose within a safe range. Intensive treatment with tight control of blood glucose has become the standard of care for diabetes. Such intensive treatment requires monitoring as part of that regimen: by knowing the blood sugar levels the patient or caregiver can adjust diet, exercise, and insulin appropriately.

Self-monitoring of blood glucose (SMBG), sometimes called intermittent monitoring, using meters which analyze small amounts of capillary blood on reagent-coated test stripes, provides immediate documentation of glycemic status. This allows one to implement strategies to address and avoid out of range glucose values. It provides only a snapshot of the blood glucose level and thus, cannot provide information on whether there is a trend toward higher or lower levels.

Minimally-invasive devices which measure interstitial fluid glucose concentration via sensors which have been inserted subcutaneously have become more widely available. These devices take samples every 1-20 minutes over the time that the device is worn. Such continuous glucose monitors (CGM) may download data to an insulin pump and/or are stored in a receiver device. CGMs may guide real-time adjustment of food and insulin. Frequent readings may assist patients in seeing if there is a trend toward increasing or decreasing glucose levels so that they can act accordingly. They may aid in identifying times of consistent hyperglycemia or increased risk of hypoglycemia. Some may sound an alarm based on specific targets values and rate of change of interstitial glucose which may facilitate initiation of the appropriate action(s) to avoid hyper- or hypoglycemic events.

The effectiveness and optimal frequency of self-monitoring of blood glucose in patients is controversial. Several lines of evidence have suggested an association between glucose monitoring and increased discomfort, inconvenience and worsening of depression scores with regular self-monitoring, along with a lack of clinically relevant improvement in diabetes-related outcomes in patients who self-test. On the other hand, children and adolescents can be especially at risk for some diabetes related complications (e.g. hypoglycemia, ketoacidosis) recommended. Information about the best options for glucose monitoring in diabetic persons 18 and under, including evidence of efficacy and safety and cost; and correlation of frequency (including strip frequency and continuous monitoring) to improved outcomes is needed.

In November 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 Glucose Monitoring report is 152 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 March 18th, 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 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 evidence based technology assessment report indicates:

- Diabetes mellitus or diabetes is a serious chronic disease characterized by elevation of blood glucose. The predominated form of diabetes in children is from an autoimmune disorder that destroys the pancreatic cells where insulin is made. There is no cure; insulin injections are required and the primary goals for treatment of youth with insulin requiring diabetes are to maintain plasma glucose and A1C levels as close to normal as possible. Diabetic ketoacidosis (very high glucose level) is the leading acute complication and can result in morbidity and mortality. A seminal diabetes study (DCCT) results suggest that maintaining near normal levels of A1C are ideal to minimize the risk of chronic complications, but the lower the A1C puts individuals at risk of severe hypoglycemia. Children and adolescents have challenges related to varying physical capability, physiological and psycho-social changes that influence metabolism and adherence to self care behaviors.
- Self monitoring of blood glucose has become a standard practice recommendation due to the link between good glycemic control and lower chronic complications; however, the method and optimal frequency of self-monitoring of blood glucose in patients remains controversial. Several lines of evidence have suggested an association between glucose monitoring and increased discomfort, inconvenience and worsening of depression scores with regular self-monitoring, along with a lack of clinically relevant improvement in diabetes-related outcomes in patients who self-test. On the other hand, children and adolescents can be especially at risk for some diabetes related complications. Information about the best options for glucose monitoring in diabetic persons 18 and under, including evidence of efficacy and safety and cost; and correlation of frequency (including strip frequency and continuous monitoring) to improved outcomes is needed.
- Self-monitoring of blood glucose (SMBG) uses meters to analyze small amounts of capillary blood on reagent-coated test strips to provide immediate documentation of glycemic status. This allows one to implement strategies to address and avoid out of range glucose values. It provides only a snapshot of the blood glucose level and thus, cannot provide information on whether there is a trend toward higher or lower levels. Continuous glucose monitors (CGM) are more recent technology where a minimally-invasive device is worn to measure interstitial fluid glucose concentration via sensors which have been inserted subcutaneously. These devices take samples every 1-20 minutes over the time that the device is worn. CGM is not approved for insulin dosing decisions, so individuals using CGM must still conduct SMBG several times a day.
- Evidence included in the technology assessment review was obtained through a structured, systematic search of the medical literature; economic studies; and clinical guidelines. 240 potentially relevant studies were identified; 49 were included; no economic studies found. The evidence is indirect because SMGB is note separately studied. Primary evidence for SMBG is 1 randomized control trial (DCCT) and 2 associated observational follow up (EDIC); 1 larger registry study and 7 cross-sectional studies. For CGM, 4 RCTs and JDRF's analysis were included, though data is not uniformly available for 18 and under.
- The evidence based technology assessment report identified six expert treatment guidelines and no National Coverage decision (NCD) policy addressing children.
- 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.

Draft Version - Not Officially Adopted: 3-18-2011

2. Is the technology 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. Summary of committee considerations follows.

- The evidence based technology assessment report indicates that the strength of evidence of safety is moderate based on number and quality of studies. SGBM and CGM have no major adverse events or deaths. (*Adverse events from severe high and low glucose are described in efficacy*).
- The evidence based technology assessment report indicates that the primary issues for SGBM are from older studies that reported sore fingers and difficulty obtaining samples.
- The evidence based technology assessment report indicates that for CGM, primary issues from small RCT and observational studies included skin irritation (0%- 53%); sensor dislodging (10% - 13%); alarms interfering with daily routine (38%) and irritation with alarms (38% - 50%). The primary safety issue with CGMs are false alerts and missed alerts (false negatives); rates varied across blood glucose thresholds and devices – false negatives rates for hypoglycemia (below threshold) ranged from 14% to 75% and false negative rates for hyperglycemia (above threshold) ranged from 5% to 37%).

3. Is the technology 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. Summary of committee considerations follows.

- Efficacy of SMBG – the evidence based technology assessment report indicated that no studies evaluated current methods of SMBG testing alone or as an independent component of diabetes management. The Diabetes Complications and Control Trial (DCCT-1994) is the primary study of 195 patients aged 13 to 17 providing indirect evidence regarding the efficacy of SMBG as part of a package of comprehensive, intensive diabetes care, which included SMBG four or more times per day and education on how to use the information to adjust insulin, diet and exercise compared with the then standard of care (urine or SMBG once/day, only periodic insulin adjustment).
 - Mean A1c levels 8.06% for intensive care arm vs. 9.7% for conventional arm; a 61% risk reduction in sustained at least three step retinopathy in intensive arm; no difference in nephrology; no difference in ketoacidosis (18% vs. 20%); and a threefold higher risk of hypoglycemia resulting in coma/seizure in intensive care arm.
- Effectiveness of SMBG – the evidence based technology assessment report indicated indirect evidence on the effectiveness of SMBG is based on the Epidemiology of Diabetes Interventions and Complications (EDIC-2001) the observational follow-up to the DCCT at four and ten years with 175 patients. All participants in the conventional treatment arm were offered instruction in the use of intensive therapy and intensive treatment group patients were encouraged to continue such treatment. No significant differences between the groups identified except related to retinopathy at 4yr.
 - Mean A1c levels 8.38% for intensive arm vs. 8.45% in conventional at 4yr; and 8.2% for both groups at 10yr;
 - Retinopathy progression worse in 7% of intensive arm vs. 25% in conventional at 4yr and 51% for intensive arm vs. 53% in conventional at 10yr;
 - Severe hypoglycemia; macular edema; and nephropathy had no significant differences
- Efficacy and effectiveness by frequency or mode of test -- there were no clinical trials that directly evaluated the efficacy of SMBG frequency. Indirect evidence from the DCCT provides information with respect to frequency in that the intensive group was instructed to test at least four times per day compared with the conventional care groups once per day (see above).

The bulk of the evidence on efficacy of mode of self-monitoring comes from comparisons with continuous glucose monitors (CGM).

- CGM used with SMBG (for calibration and verification per FDA recommendations) was compared with SMBG alone; three RCTs form primary basis; overall *Strength of Evidence is low*. Data from one JDRF 2008 report on CGM (result stratified by age (n = 114, 8-14 year olds)) and one smaller Hirsch RCT (n = 40, 12-18 year olds) are primary studies. Another JDRF (2009) study has few outcomes stratified by age. In the JDRF studies, 84% of both CGM and SMBG groups used insulin pumps (which did not communicate with the CGM) and 100% of patients in the Hirsch study used pumps integrated with the CGM device in the CGM arm only. Different in population and study design preclude pooling of data.
 - Mean differences in HbA1C levels were not clinically or statistically significant in short term.
 - No study reported significant differences in episodes of hypoglycemia for CGM vs. SMBG.
 - 2 RCTs reporting on hyperglycemia reported no significant differences for CGM vs. SMBG.
 - Results on the effect of CGM vs. SMBG on medication or nutritional management conflicted: 2 studies reported significant differences in insulin doses where one study reported no change in insulin doses.
- There are currently no long-term comparative studies on these devices for evaluation of benefits, complications or diabetes-related co-morbidities on those ≤ 18 years old.

4. **Special Populations?**

- The evidence based technology assessment report reported one RCT and one large registry study directly assessed differential outcomes for either CGM or SMBG by age subpopulations. The overall strength of evidence is low.
- The evidence based technology assessment report included one RCT comparing CGM with SMBG in patients 8-14 years old and those 15-24 years old - each had similar results with regard to A1C and achieving targets for CGM and SMBG with no evidence of differential efficacy by age was demonstrated.
- The evidence based technology assessment report reported that there is limited evidence for differential effect of frequency of SMBG testing by age from one large registry study.
 - For 13-18 year olds an average improvement in A1C of 0.3% ± 0.011 for each additional SMBG was reported. This appears to apply up to tests five per day.
- In contrast, for ages 0-5 and 6-12, beyond one test per day, improvement in A1C was much less and averaged 0.04% ± 0.018 and 0.12% ± 0.010 respectively beyond one SMBG per day.

5. **Is the technology 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 assessment report indicated that no evidence is available to assess the cost effectiveness of SMBG or CMG in persons with diabetes ≤18 years old who require insulin. No full economic studies which focused on the cost-effectiveness of CGM or the frequency of SMBG were found.

6. **Medicare Decision and Expert Treatment Guidelines**

Committee reviewed and discussed the expert guidelines as identified and reported in the technology assessment report.

- Centers for Medicare and Medicaid Services (CMS) – no NCD policy addressing children.
 - For adults, to be eligible for coverage of home blood glucose monitors and related accessories and supplies, the patient (or patient’s care-giver) must meet all the following criteria:
 - Diagnosed with diabetes that is being treated by a physician
 - Glucose monitor and related supplies ordered by the treating physician with documentation of medical necessity for the prescribed frequency of testing
 - Successfully completed training or is scheduled to begin training in the use of these items
 - Capable of using the test results to assure appropriate glycemic control
 - Device is designed for home use
 - Supplies covered: Up to 100 test strips and lancets every month for beneficiaries who are insulin dependent and every 3 months for those who are non-insulin dependent, and one lancet device every 6 months for both indications.
- Guidelines – the evidence based technology assessment report identified six guidelines though a search of the *National Guideline Clearinghouse*.
 - American Diabetes Association (ADA), 2010 – Frequency of self-monitored blood glucose (SMBG): SMBG in general has been extensively reviewed by the ADA and is recommended for patients of all ages with type 1 diabetes. The 2010 report did not specifically address frequency for children; however, in a statement published in 2005 by the ADA entitled Care of Children and Adolescents with Type 1 Diabetes it is recommended that SMBG be performed at least four times daily. *Continuous glucose monitoring (CGM)*: CGM in conjunction with intensive insulin regimens can be a useful tool to lower A1c in selected adults (age ≥ 25 years) with type 1 diabetes. Although the evidence for A1c lowering is less strong in children, teens, and younger adults, CGM may be helpful in these groups. Success correlates with adherence to ongoing use of the device. CGM may be a supplemental tool to SMBG in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes. *Glycemic goals*: consider age when setting glycemic goals in children and adolescents with type 1 diabetes, with less stringent goals for younger children.
 - Diabetes Coalition of California, California Diabetes Program, 2008 – this guideline addresses adults, children and adolescents with type 1 and type 2 diabetes mellitus. *SMBG testing*: typically test at least 4x / daily. *Lab exams*: A1c should be checked 1-2 times year if stable, quarterly if treatment changes or if not meeting goals. Target goal < 7.0% or < 1% above lab norms. For children, modify as necessary to prevent significant hypoglycemia. Furthermore, microalbuminuria should be checked beginning with puberty once the duration of diabetes is > 5 years unless proteinuria has been documented. *Self-care behaviors*: as appropriate for child’s developmental stage.
 - International Society for Pediatric and Adolescent Diabetes (ISPAD), 2009 – In summary, SMBG is an essential tool in the optimal management of childhood and adolescent diabetes and, when financially possible, should be made available for all children with diabetes. The cost of BG monitoring is very expensive and in many countries the cost relative to the cost of living may make this technology unavailable. *Frequency of SMBG*: SMBG should be prescribed at a frequency to optimize each child’s diabetes control, usually 4-6 times a day, because frequency of SMBG correlates with glycemic control. *CGM*: CGM devices are becoming available that may particularly benefit those with hypoglycemic unawareness, as the devices will alarm when glucose is below a specified range or with rapid rate of fall of glucose. *Glycemic goals*: the target

-
- A1c for all child age-groups is recommended to be < 7.5%. Every child should have a minimum of one measurement of A1c per year. Ideally, there should be four to six measurements per year in younger children and three to four measurements per year in older children.
- National Institute for Health and Clinical Excellence (NICE), 2004 -- *SMBG*: who are trying to optimize their glycemic control and/or have intercurrent illness should be encouraged to measure their blood glucose levels more than four times per day. Should be encouraged to perform frequent blood glucose monitoring as part of a continuing package of care that includes dietary management, continued education and regular contact with their diabetes care team. *CGM*: who have persistent problems with hypoglycemia awareness or repeated hypoglycemia or hyperglycemia should be offered CGM systems. *Glycemic goals*: should be encouraged to use blood glucose measurements for short-term monitoring of glycemic control. The target for long-term glycemic control is an A1c level of less than 7.5% without frequent disabling hypoglycemia and the child's care package should be designed to attempt to achieve this.
 - American Association of Clinical Endocrinologists (AACE), 2010 – Personal CGM is recommended for patients with type 1 DM and following characteristics: hypoglycemic unawareness or frequent hypoglycemia; A1c over target, or with excess glycemic variability; requiring A1c lowering without increased hypoglycemia; during preconception or pregnancy. Personal CGM use is recommended for children and adolescents with type 1 DM who have achieved A1c levels less than 7.0%; youth with type 1 DM who have A1c levels of 7.0% or higher and are able to use the device on a near-daily basis. The following patients might be good candidates for personal CGM, and a trial of 2 to 4 weeks is recommended: youth who frequently monitor their blood glucose levels; committed families of young children (< 8 years old), especially if the patient is having problems with hypoglycemia.
 - British Society of Pediatric Endocrinology, 2009 – *Proven clinical indication*: to lower A1c, when this remains above the individual's target despite optimized use of intensive insulin regimens. *Potential clinical indications – Diagnostic*: suspected nocturnal hypoglycemia and/or early morning hyperglycemia; suspected unrecognized hypoglycemia; A1c above individualized target despite intensified insulin therapy apparently optimized with self-monitoring; persistent disabling hypoglycemia despite conversion from MDI to CSII. *Potential clinical indications – Therapeutic*: further optimization of pump therapy regimens when A1c cannot be consistently lowered below 7.5%; protection against recurrent disabling hypoglycemia, and for those with hypoglycemia unawareness or debilitating fear of hypoglycemia.

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 Glucose Monitoring demonstrates that there is sufficient evidence to cover self-monitoring of blood glucose (SMBG) for insulin dependent individuals under the age of 19. The committee agreed that there is sufficient evidence on continuous glucose monitoring for insulin dependent individuals under the age of 19 to cover with conditions. 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 to cover self-monitoring of blood glucose (SMBG). Based on these findings, the committee voted to cover with conditions continuous glucose monitoring (CGM).

Health Technology Clinical Committee Authority

Washington State's legislature believes it is important to use a scientific based, clinician centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority, through its Health Technology Assessment program to engage in a process for evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and takes public input at all stages. Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State Health Technology Clinical Committee (HTCC) determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases their decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.

Glucose Monitoring

Draft Findings & Decision Timeline and Overview of Comments

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on Glucose Monitoring.

Commenter	Comment Period April 26 – May 10	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Physician and health care professional	0	0
Industry and Manufacturer	1	0
Professional Society and Advocacy Organization	0	0

All Total = 1

Comments without Evidence:

Industry and Manufacturer Comments

Carrie Hartgen, Vice President, State Government Relations & Regional Affairs, AdvaMed -- Advanced Medical Technology Association

- Requested clarification on the HTCC draft coverage determination language on Glucose Monitoring, specifically requesting if any strip limitations were set by the committee.

	Actual Timeline	Total Public Comment Days
Preliminary recommendations published	October 15, 2008	
Public comments due:	October 31, 2008	17 days
Third seven topics published:	December 12, 2008	
Public comments due:	January 16, 2009	36 days
Draft Key Questions Published:	April 23, 2010	
Public comments due:	May 7, 2010	15 days
Key Questions Finalized:	June 21, 2010	
Draft report due:	November 9, 2010	
Draft report published:	November 12, 2010	
Public Comments due:	December 10, 2010	29 days
Final report due:	January 13, 2011	
Final report published:	January 14, 2011	
Public meeting Date:	March 18, 2011	
Findings & Decision Published	April 26, 2011	
Public Comments due:	May 10, 2011	15 days

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May 9, 2011

Ms. Leah Hole-Curry
Washington Health Technology Assessment Program
P.O. Box 42712
Olympia, WA 98504-2712

Dear Ms. Hole-Curry:

I am writing to seek clarification on the Draft Findings and Decisions on the Health Technology Clinical Committee report on Glucose Monitoring.

Specifically, the motion and vote at the March 18 Health Technology Clinical Committee meeting was to unconditionally approve unlimited test strips for glucose monitoring for patients under 19 years of age. Unfortunately, our read of the Draft Findings and Decisions Report does not reflect that HTCC decision. Specifically, it is unclear as to whether "no conditions" means unlimited access to strips. Your clarification of this important issue in your final decision in writing is most appreciated.

The Advanced Medical Technology Association (AdvaMed) is the national association of manufacturers of medical devices and diagnostics. Our members are responsible for the life-saving and life-enhancing advances that are improving health care and lowering costs.

AdvaMed is strongly committed to the principles of evidence-based medicine and supports collaborative efforts to obtain evidence that can be used to assist patients and physicians in making medical decisions that are optimal for the individual patient. Supporting optimal medical decision-making is clearly aligned with the goals of improving quality and efficiency in the delivery of health care services.

I look forward to your response. If you have an immediate questions, please contact me at (202)434-7265.

Sincerely,



Carrie Hartgen

**Health Technology Clinical Committee
Findings and Coverage Decision**

Topic: Spinal Injections
Meeting Date: March 18th, 2011
Final Adoption:

Number and Coverage Topic

20110318B – Spinal Injections

HTCC Coverage Determination

Nerve Block Injections, Intradiscal Injections and Facet Injections are **not a covered benefit**

Lumbar Epidural Injections; Cervical-thoracic Epidural Injections and Sacroiliac Joint Injections are a **covered benefit** for the treatment of chronic spinal pain and associated radiculopathies

HTCC Reimbursement Determination

❖ **Limitations of Coverage**

For treatment of chronic spinal pain and associated radiculopathies:

- Therapeutic Epidural Injections in the lumbar or cervical-thoracic spine for chronic pain is a covered benefit when all of the following conditions are met:
 - For treatment of radicular pain
 - With fluoroscopic guidance or CT guidance
 - After failure of conservative therapy
 - No more than two without clinically meaningful improvement in pain and function, and
 - Maximum of 3 in 6 months
- Therapeutic Sacroiliac Joint Injections for chronic pain is a covered benefit when all of the following conditions are met:
 - With Fluoroscopic guidance or CT guidance
 - After failure of conservative therapy, and
 - No more than one without clinically meaningful improvement in pain and function, subject to agency review

❖ **Non-Covered Indicators**

- Nerve block injections; intradiscal injections and facet injections are not a covered benefit.

❖ **Agency Contact Information**

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

Health Technology Background

The Spinal Injections topic was selected and published in December 2009 to undergo an evidence review process. The evidence based technology assessment report indicates that an estimated 75% of the population has had an episode of back pain at some point in their life. While most acute back pain resolves within a few months, surveys report that approximately 5% of the population has chronic back pain, a percentage which implicates significant social and economic impacts. The risk of spinal pain increases with age as a result of disc disease and spinal degeneration. Those affected can have disabling symptoms that can dramatically affect their quality of life and ability to perform a variety of activities. Chronic spinal pain can be attributed to a number of pathologies, including (but not limited to) degenerative disc disease (DDD), herniated nucleus pulposus (HNP) (or herniated/slipped disc), spinal stenosis, radiculopathy, failed back surgery syndrome (FBSS), facet joint syndrome, and whiplash.

Treatment for chronic back pain typically begins with the identification of the underlying cause of pain and follows with conventional medical management (CMM), which varies with the diagnosis. CMM may include conservative/ non-invasive interventions such as physical therapy and rehabilitation, pharmaceutical pain management, psychological therapy and coping skills, exercise, education, antidepressants, cognitive behavioral therapy and supported self-management, spinal manipulation, electrical stimulation, injections outside the spine, implanted devices, acupuncture/acupressure, and modified work.

Patients who don't respond to non-invasive treatment are typically referred for more invasive and non-surgical therapies such as spinal injections in an attempt to provide pain relief. Spinal injections involve the injection of an anti-inflammatory agent such as a steroid and/or an anesthetic into the spine or space around the spinal nerves and joints. One of the theoretical advantages of spinal injections is that they deliver the treatment medication directly to the site involved in the source of pain. Types of spinal injection include epidural, facet joint, intradiscal, and sacroiliac joint injections. Spinal injections can be used for diagnostic and therapeutic purposes.

In November 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 Injections report is 299 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 March 18th, 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 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 Spinal Injections has been collected and summarized. The evidence is presented below:

- The evidence based technology assessment report estimates 75% of the population has an episode of back pain at some point in their life. While most acute back pain resolves within a few months, surveys report that approximately 5% of the population has chronic back pain, with significant social and economic impacts. Those affected can have disabling symptoms that can dramatically affect their quality of life and ability to perform a variety of activities. The source and pathology of chronic spinal pain is not well understood but has been attributed degenerative disc disease (DDD), herniated nucleus pulposus (HNP) (or herniated/slipped disc), spinal stenosis, radiculopathy, failed back surgery syndrome (FBSS), facet joint syndrome, among other causes.
- The evidence based technology assessment report indicates treatment for chronic back pain typically begins with the identification (or ruling out) of underlying cause of pain and beginning conventional medical management (CMM). CMM may include conservative/ non-invasive interventions such as physical therapy and rehabilitation, pharmaceutical pain management, psychological therapy and coping skills, exercise, education, antidepressants, cognitive behavioral therapy and supported self-management, spinal manipulation, electrical stimulation, injections outside the spine, implanted devices, acupuncture/acupressure, and modified work.
- The evidence based technology assessment report indicates that a small percentage of non-responsive patients may proceed to invasive therapies, including spinal injections. Spinal injections are not curative but are intended to provide pain relief and functional improvement for up to several months. Spinal injections involve the injection of an anti-inflammatory agent such as a steroid and/or an anesthetic into the spine or space around the spinal nerves and joints. One of the theoretical advantages of spinal injections is that they deliver medication directly to the site thought to be the source of pain. Types of spinal injection include epidural, facet joint, intradiscal, and sacroiliac joint injections. Spinal injections can be used for diagnostic and therapeutic purposes. According to one study examining Medicare claims of lumbosacral injections, the number of epidural steroidal injections increased 271% and the number of facet injections increased 231% from 1994 to 2001. A similar study found that lumbar facet joint injections/diagnostic blocks increased 161% from 2002 to 2006.
- Despite dramatic growth in procedures, evidence about the impact of spinal injections on important patient oriented outcomes related to impact on pain, physical function, opioid use; return to work; quality of life; patient satisfaction; avoidance of more invasive surgery; expected duration of impact; need for repeat procedures; frequency and type of harms; as well as clinical impacts of multilevel or procedure differences and any evidence about differential effect based on different patient, social or provider characteristics; different injection types; and impact of cost is needed.
- The evidence based technology assessment report indicates that the Spinal injection evidence base is extensive: initial search resulted in over 2,700 potential citations; and based on evaluation against inclusion criteria, 1 Systematic review; 22 RCTs, 24 Observational Studies and two economic studies were included.
 - Evidence was identified on five injection types: epidural (lumbar and cervical); facet joint; sacroiliac; intradiscal injections and medial branch blocks.
 - Key strengths of the overall body of evidence are a large evidence base including randomized clinical trials.

- Limitations in the overall body of evidence: despite well validated measures to evaluate treatment outcomes, evidence is limited by the variety of different measures or non-validated measures used; most studies were limited by a focus on one outcome - impact on short term pain; studies not including a placebo arm are limited when measuring subjective improvement in pain; many studies were limited by short duration (3 month or less) for treatment of a chronic condition; there remains uncertainty over clinically meaningful improvement for pain and function; and the variety of injection methods and types.

2. Is the technology 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. Summary of committee considerations follows.

- Major Complications: the evidence based technology assessment report indicated that major reported complications of spinal injection include dural puncture; subarachnoid puncture and angina pectoris, though rates are rare.
 - There were no cases of death or paralysis related to the procedure in the included studies, though death unrelated to the procedure was reported in 10 of 1146 patients in the RCTs, and there have been case reports of death and paralysis in the published literature.
 - For dural or subarachnoid punctures, or other life threatening complications, the reported rates ranged from 3 in 710 injections to 5 in 7240 (cervical) and 1 in 1556 injections to 1 in 10,416 injections for lumbar.
 - Vascular Puncture: the evidence based technology assessment report indicated the mean incidence of intravascular puncture following fluoroscopically guided lumbar spinal injections was 10.18% (range, 1.9–22%) as reported in five case series designed to assess its incidence.
- Minor Complications: the evidence based technology assessment report indicated that minor complications are more common but are generally transient in nature. The overall minor complication rate ranged from 0.06% to 16.3% of injections or patients in 19 RCTs and 14 case series, and complications included: pain at the injection site, increased radicular pain/numbness/weakness, nerve root irritation, superficial infections, sympathetic blockade, facial flushing, vasovagal reactions/fainting, headache, gastric complaints, dizziness, pruritis, irregular periods, and insomnia.
- Radiation Exposure to the Physician: the evidence based technology assessment report indicated the with proper protective measures, total radiation exposure was within normal limits following a mean of 923 procedures (range, 100 – 1819) with an average length of radiation exposure of 9.8 seconds/procedure (range, 4.9 – 15.2) in all five case series we identified.
 - The evidence based technology assessment report reported that approximately 50% of four million interventional medical procedures per year are performed under fluoroscopic guidance. Fluoroscopy for spinal injections is routinely used to ensure correct needle placement, accurate delivery of the injectate, and avoidance of complications. Incorrect needle placement during spinal injections without the use of fluoroscopy has been reported by various studies in 12.5% to 38.3% of patients. A C-arm fluoroscope allows the X-ray tube to be moved around the prone patient and an image intensifier enhances the image, making it easier to interpret. Although studies have shown that radiation exposure to physicians using fluoroscopy for spinal injections is within safety limits, other methods, including ultrasound and CT, are being investigated as non-radioactive or lower radioactive methods of needle guidance.

3. Is the technology 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. Summary of committee considerations follows.

- Discussion focused on the following categories of injections: lumbar epidural; cervical/thoracic epidural; facet joint injection; sacroiliac joint injection; medial branch block; and intradiscal injection. Further differentiation was not focused on as the evidence based technology report indicated low to very low overall strength of evidence of different impact. The low level of evidence reported no consistent differential impact based on the approach to administering the injection; the diagnosis, pre-injection pain intensity; type of steroid, gender, age or other patient characteristics.
- **Epidural Steroid Injections for lumbar or low back pain with sciatica or radiculopathy** was highly studied and reported on; however, the overall strength of evidence is low based on the individual trial limitations and the inconsistency in results. Low back pain with sciatica or radiculopathy *the evidence is mixed* about the impact of spinal injection on pain (and in some studies function); with some studies showing a inferior results compared to placebo or other interventions and some studies showing a positive result.
 - When compared to placebo for caudal or interlaminar: *In the short-term* (≤ 3 months) there was mixed evidence based on data from twenty RCTs, seventeen of which were included in the Chou/APS SR (seven were considered to be higher-quality trials). Seven of seventeen studies included in the SR reported no benefit or inferior results while another seven reported positive results and three reported unclear results. Three LoE IIb RCTs published after the SR were added here, two reported on pain (both negative) and three on function (two negative and one positive) at three months. *In the long-term* (> 3 months) there was mixed evidence based on data from twelve RCTs, nine of which were included in the Chou/APS SR. Seven of nine studies included in the SR reported no benefit or inferior results while positive results were reported by one study and another reported mixed results. Regarding the more recent RCTs included here, two reported on pain (both negative at twelve months, although one was positive at six months) and three on function (mixed results, one positive, one mixed, and one negative). (SoE = Low)
 - When compared to placebo for transforaminal: mixed evidence based on data from four RCTs, two of which were included in the Chou/APS SR and considered to be higher-quality and two of which were more recent LoE IIb studies. In terms of pain relief, the data suggest a benefit at two weeks (one study), mixed results at one month (two studies- one positive and one negative), and no benefit by 3 months. No benefit in function was reported at three months by two studies. Long-term data were mixed as reported by two higher-quality RCTs, both of which were reported in the Chou/APS SR, with one study reported positive results while the other showed no benefit. When compared to intramuscular injections, transforaminal steroid injections were superior to intramuscular injections in terms of pain relief at one month based on data from one LoE IIb RCT. (SoE = Low)
- **Epidural Steroid Injections for lumbar or low back pain without sciatica or radiculopathy** was also studied and reported on, and the overall strength of evidence is low to moderate based on the individual trial limitations and indication studied. The evidence indicates *no benefit* of spinal injections compared either to placebo, physical therapy, trigger point injection, discectomy or dry needling.
 - Low back pain (without sciatica or radiculopathy) compared to placebo showed no benefit based on data from three RCTs, one of which was included in the Chou/APS SR

- and considered to be a lower-quality trial. The two more recent RCTs rated IIb also reported no benefit in pain, function, or opioid use at three months or in employment at twelve months. (SoE = Moderate)
- Spinal Stenosis compared to placebo: *In the short-term* (24 hours – 3 months), there was no benefit based on data from four RCTs, three of which was included in the Chou/APS SR; one was considered to be a higher-quality trial. Three of four studies reported no benefit; one study reported improved walking distance at one week. In a recent RCT, LoE IIb there was no benefit in pain, function, or opioid use at three months. (SoE = moderate). *In the long-term* (13 – 30 months), there was no benefit based on data from two RCTs as reported in the Chou/APS SR. (SoE = Low)
 - Failed back surgery syndrome compared to placebo: no benefit based on data from three RCTs, two of which were included in the Chou/APS SR and considered to be lower-quality trials. In the one recent LoE IIb RCT, there was no benefit in pain, function, or opioid use at three months. (SoE = Moderate)
 - Spinal Stenosis compared to physical therapy or control: no benefit in terms of pain, function, or quality of life at three and six months based on data from one LoE IIb RCT. (SoE = Very Low)
- **Epidural Steroid Injections for cervical pain** reported overall strength of evidence of very low based on small number of trials, trial limitation and inconsistent results. The evidence indicates *mixed benefit* of epidural cervical spinal injections.
 - For neck pain with disc herniation and radiculitis (comparator = placebo): *no benefit* in terms of pain, function, or opioid use at both three and twelve months or on employment at twelve months based on data from one LoE IIb RCT. (SoE = Very Low)
 - Neck pain without disc herniation and radiculitis (comparator = placebo): *no benefit* in terms of pain, function, or opioid use at both three and twelve months or on employment at twelve months based on data from one LoE IIb RCT. (SoE = Very Low)
 - Neck pain with disc compression and radiculitis (comparator = intramuscular injection): epidural injections were *superior* to intramuscular injections in the posterior neck in terms of pain, analgesic use, and employment at one week and twelve months based on data from one LoE IIb RCT. (SoE = Very Low)
 - Facet Joint Steroid Injections overall had low strength of evidence of no benefit based on four RCTs.
 - Confirmed or presumed lumbar facet joint pain compared to placebo: no benefit in the first three months based on data from two RCTs included in the Chou/APS SR, one of which was considered to be lower-quality. Although one of the studies reported a statistically meaningful benefit at six months in patient improvement following steroid injection, the rationale for this late response is not clear. (SoE = Low)
 - Non-radicular back pain and facet joint osteoarthritis compared to hyaluronic acid: no benefit in the injection of steroids versus hyaluronic acid into the facet joint at six months based on data from one higher-quality RCT included in the Chou/APS SR. (SoE = Low)
 - Confirmed cervical facet joint pain compared to placebo: no benefit in terms of the length of pain relief based on data from one LoE IIb RCT. No long-term data was reported. (SoE = Very Low)
 - Sacroiliac Joint Steroid Injections had low overall strength of evidence of benefit based on one RCT.
 - For sacroiliac Joint Pain, compared to placebo: sacroiliac joint injections were superior to placebo injections based on data from one higher-quality RCT included in the Chou/APS SR. (SoE = Low)

- Intradiscal Injections overall had moderate strength of evidence of no benefit based on seven RCTs.
 - For discogenic back pain, steroid injection compared to placebo: no benefit based on data from three RCTs included in the Chou/APS SR, one of which was higher-quality. (SoE = Moderate)
 - For sciatica compared to chemotherapy: no benefit based on data from three RCTs included in the Chou/APS SR, one of which was higher-quality. (SoE = Moderate)
 - For low back pain without radiculopathy using neurolytic agent compared to placebo: intradiscal injections with methylene blue were superior to placebo injections in terms of pain, function, patient satisfaction, and analgesic use in the long-term (6-24 months) based on data from one LoE IIa RCT. (SoE = Low)
- Medial Branch Blocks overall had low to very low strength of evidence of no benefit based on four RCTs.
 - For confirmed lumbar facet joint pain compared to placebo: no benefit in terms of pain or function at both three and twelve months or on opioid use at twelve months based on data from one LoE IIb RCT. (SoE = Very Low)
 - For presumed lumbar facet joint pain compared to Sarapin: no benefit in injections with Sarapin with or without steroid based on data from one higher-quality and one lower-quality RCT included in the Chou/APS SR. (SoE = Low)
- For confirmed cervical facet joint pain compared to placebo: no benefit in terms of pain or function at both three and twelve months or on opioid use or employment at twelve months based on data from one LoE IIb RCT. (SoE = Very Low)

4. **Special Populations?**

- Approach of the Epidural Steroid Injection: the evidence based technology assessment report indicated no consistent evidence from a systematic review of six RCTs and two additional RCTs published since the systematic review that one approach is more efficacious in administering lumbar epidural steroid. The results of one lower quality RCT suggest that interlaminar injections may not be as efficacious as transforaminal in patients with axial only pain from spinal stenosis. However, more study is needed to verify these findings.
- Diagnosis: the evidence based technology assessment report indicated no consistent evidence that epidural steroid injections have differential efficacy or effectiveness among various diagnoses of the lumbar or cervical spine.
- Pre-injection pain intensity or duration, type of steroid, sex, age, or MRI findings: the evidence based technology assessment report indicated no consistent evidence that pre-injection pain intensity or duration, type of steroid used as injectate, sex, age or pre-injection MRI findings are associated with outcome in patients receiving epidural steroid injections of the lumbar or cervical spine.

5. **Is the technology 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 assessment report reported no evidence that epidural steroid injections are cost effective based on data from two economic analyses. One moderately well conducted cost utility analysis (QHES 78/100) suggested that one epidural steroid injection is a more cost effective patient management strategy than up to three injections and that cost effectiveness ratios for epidural steroid injections are too high to be considered cost effective by

UK conventions. Further, the budget impact of epidural spinal injections is likely large because of high use. Poor economic data (QHES 49/100) from a second trial (Karppinen) suggested that over one year epidural steroid injections do not show cost or outcome advantages compared to saline injections, and that contained herniations may be more responsive to steroid injection than bulges or extrusions.

- The evidence based technology assessment report reported no economic data were available for facet injections, medial branch blocks, sacroiliac joint injections, or intradiscal injections or for any type of cervical injection.
 - Washington state agency utilization and cost information indicated costs for Spinal Injections of \$55M for the past four years with a rising trend.

6. Medicare Decision and Expert Treatment Guidelines

Committee reviewed and discussed the Medicare Decision and expert guidelines as identified and reported in the technology assessment report.

- The Centers for Medicare and Medicaid Services have no published National coverage determinations (NCD) for any spinal injections.
- Guidelines – a search of the core sources and relevant specialty groups identified fourteen guidelines.
 - American Pain Society (APS), 2009: For patients with nonradicular low back pain, the APS is unable to assess the benefit of epidural steroid injection, facet joint steroid injection, medial branch block, or sacroiliac joint injection based on insufficient or poor evidence. Corticosteroid facet joint injection is not recommended based on moderate evidence. Intradiscal steroid injection is not recommended for treatment of nonradicular low back pain based on good evidence. For patients with radicular low back pain, the APS found moderate evidence for short-term (through three months) benefit from epidural steroid injections based on fair evidence. A recommendation for epidural steroid injection for patients with symptomatic spinal stenosis is not offered based on insufficient or poor evidence.
 - American Society of Interventional Pain Physicians, 2009: The recommendation for caudal epidural steroid injection in managing lumbar spinal pain with disc herniation and radiculitis or discogenic pain without disc herniation or radiculitis is 1A or 1B, indicating a strong recommendation where the benefits outweigh the risks of treatment. In addition, the recommendation for caudal epidural steroid injection for patients with post-lumbar laminectomy syndrome and spinal stenosis is 1B or 1C, also indicating a strong recommendation. The recommendation for use of cervical interlaminar epidural injection for disc herniation and radiculitis to achieve short-term relief is 1C. For patients seeking long-term relief, the recommendation is 2B (weak recommendation), indicating benefits are balanced with risks and burdens of treatment. In patients with spinal stenosis and discogenic pain without disc herniation and radiculitis the recommendation is 2C (very weak, with uncertainty in estimates of benefits, risk, and burden of treatment). The recommendation for lumbar transforaminal epidural injections is 1C. Intraarticular facet joint injections are not recommended. Cervical, thoracic, and lumbar facet joint nerve blocks are recommended to provide both short-term and long-term relief in the treatment of chronic facet joint pain (recommendation 1B or 1C).
 - Institute for Clinical Systems Improvement (ICSI), 2009: Epidural steroid injections and facet joint injections are classified as level I (standard, first-line) therapeutic procedures, and are recommended as part of a comprehensive treatment plan that includes pharmacologic, rehabilitative, and psychological interventions. Evidence is limited when such procedures are used alone.

- American College of Occupational and Environmental Medicine (ACOEM), 2008: Epidural glucocorticosteroid injection is recommended as a treatment option for subacute radicular pain syndromes, and as an option for second-line treatment of acute flare-ups of spinal stenosis associated with true radicular or radiculomyelopathic symptoms based on low potential harm to the patient and low costs (Evidence Rating I: insufficient evidence). Epidural glucocorticosteroid injection is not recommended to treat chronic neck pain or for dorsal spine symptoms that predominate over leg pain based on evidence that harms and cost exceed benefits to the patient (Evidence Rating C: limited evidence). The ACOEM makes no recommendation regarding the use of facet joint injection for flare-ups of neuropathic pain or chronic low back pain (Evidence Rating I: insufficient evidence). Facet joint injection is not recommended for any radicular pain syndrome, chronic non-specific axial pain, and repeat injections are not recommended for patients who failed to achieve lasting functional improvements after a prior injection for neuropathic or chronic low back pain based on evidence that treatment is ineffective or that costs or harms outweigh benefits to the patient (Evidence Rating B: moderate evidence).
- Institute for Clinical Systems Improvement (ICSI), 2008: ICSI recommends epidural steroid injection only after conservative treatment has failed and to avoid surgical intervention. ICSI finds limited evidence for the efficacy of epidural steroid injection, but indicates it may allow patients to progress with conservative treatments. Epidural steroid injection should be performed under fluoroscopy with contrast in order to prevent treatment failure.
- Work Loss Data Institute, Low back – lumbar & thoracic (acute & chronic), 2008: Epidural steroid injection and sacroiliac joint injections are recommended as part of a comprehensive treatment plan for low back pain. Specifically, epidural steroid injection is recommended to avoid surgery for severe cases with radiculopathy, but does not offer long-term functional benefit. “Series of three” epidural steroid injections, facet joint injection (multiple series, thoracic, and medical branch blocks), and intradiscal steroid injection were considered but are not recommended.
- Work Loss Data, Neck and upper back (acute & chronic), 2008: Epidural steroid injection is recommended as part of a comprehensive treatment plan for radicular pain. Specifically, epidural steroid injection is recommended to avoid surgery in severe cases with neurologic findings. Facet joint injection was considered but is not recommended.
- Work Loss Data, Pain (chronic), 2008: Epidural steroid injection is recommended as part of a comprehensive treatment plan. Facet blocks are classified as under study by the Institute and are not currently recommended.
- American Academy of Neurology, 2007: The American Academy of Neurology indicates the use of epidural steroid injections may result in a small magnitude of improvement in radicular lumbosacral pain when evaluated 2-6 weeks post-injection, but the recommendation is classified as a level C (possibly effective) due the small number of relevant studies, highly select patient population, and variation in comparison treatments in the evidence base. Epidural steroid injections are not recommended for radicular lumbosacral pain due to a lack of evidence for improvement of function, need for surgery or long-term pain relief beyond 3 months. This recommendation is classified as level B (probably ineffective based on Class I-III evidence). There was insufficient evidence to make a recommendation regarding the use of epidural steroid injections to treat cervical radicular pain.
- American College of Occupational and Environmental Medicine, 2007: The use of epidural glucocorticosteroid injection is recommended as a second-line treatment of acute spinal stenosis flare-ups, and as a treatment option for acute or subacute radicular

- pain syndromes lasting at least 3 weeks after treatment with NSAIDs and when pain is not trending towards spontaneous resolution. Both treatments are recommended based on low potential harm to the patient and low costs (Evidence Rating I: insufficient evidence). The use of facet joint injections is not recommended for acute, subacute, chronic low back pain, and radicular pain syndrome based on evidence that the treatment is ineffective or that harms and cost exceed benefits to the patient (Evidence Rating B: moderate evidence). Sacroiliac joint corticosteroid injection is recommended as an option for patients with specified known cause of sacroiliitis (Evidence Rating C: limited evidence). The use of epidural glucocorticosteroid injection is not recommended for acute, subacute, or chronic low back pain in the absence of radicular signs and symptoms (Evidence Rating C: limited evidence).
- American College of Physicians and the American Pain Society, 2007: Epidural steroid injection is an option for patients with prolapsed lumbar disc with persistent radicular symptoms who have not responded to noninvasive therapy. No specific recommendation is given for this or any other injection therapy of interest.
 - North American Spine Society (NASS), 2007: The NASS recommends nonfluoroscopically-guided interlaminar epidural steroid injection as a treatment option for short-term symptom relief in patients with neurogenic claudication or radiculopathy. A single radiographically-guided transforaminal injection may also provide short-term symptom relief for patients with radiculopathy (Grade B: fair evidence). A multiple injection regimen of radiographically-guided transforaminal epidural steroid injection or caudal injections may provide long-term symptom relief in patients with radiculopathy or neurogenic intermittent claudication, but evidence supporting this recommendation is of poor quality.
 - EuroCOST: European evidence-based guideline COST B13 Working Group on Guidelines for Chronic Low Back Pain, 2006: Epidural steroid injection, facet joint injection, and facet nerve blocks are not recommended based on a lack of evidence or conflicting evidence. Intradiscal injections are not recommended for the treatment chronic nonspecific low back pain based on evidence they are not effective (level B: moderate evidence).
 - American Association of Neurological Surgeons; Congress of Neurological Surgeons, 2005: Lumbar epidural injections and facet injections are recommended as treatment options for temporary, symptomatic relief in some patients with chronic low back pain, but epidural injections are not recommended for long-term relief of pain, based on Class III evidence (unclear clinical certainty). Facet injections are not recommended as long-term treatment for low back pain based on Class I evidence (high clinical certainty).

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 Injections demonstrates that there is sufficient evidence to cover with conditions the use of therapeutic Epidural injections in the lumbar or cervical-thoracic spine for chronic pain.
- The committee concluded that the current evidence on Spinal Injections demonstrates that there is sufficient evidence to cover with conditions therapeutic Sacroiliac joint injections for chronic pain.

- The committee concluded that the current evidence on Spinal Injections demonstrates that there is insufficient evidence to cover the other therapeutic spinal injections: Facet joint injections; medial branch block injections; and Intradiscal injections.

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 to cover with conditions lumbar epidural injections. Based on these findings, the committee voted to cover with conditions cervical-thoracic epidural injections. Based on these findings, the committee voted to not cover medial branch blocks. Based on these findings, the committee voted to not cover Intradiscal injections. Based on these findings, the committee voted to not cover facet injections. Based on these findings, the committee voted to cover with conditions Sacroiliac joint injections.

Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, therapeutic Epidural Injections in the lumbar or cervical-thoracic spine is a covered benefit when all of the following conditions are met:

- For treatment of radicular pain
- With fluoroscopic guidance or CT guidance
- After failure of conservative therapy
- No more than two without clinically meaningful improvement in pain and function
- Maximum of 3 in 6 months

Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, therapeutic Sacroiliac Joint Injections for chronic pain is a covered benefit when all of the following conditions are met:

- With Fluoroscopic guidance or CT guidance
- After failure of conservative therapy
- No more than one without clinically meaningful improvement in pain and function, under agency review

Health Technology Clinical Committee Authority

Washington State's legislature believes it is important to use a scientific based, clinician centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority, through its Health Technology Assessment program to engage in a process for evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and takes public input at all stages. Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State Health Technology Clinical Committee (HTCC) determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases their decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.

Spinal Injections

Draft Findings & Decision Timeline and Overview of Comments

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on Spinal Injections. A summary is below, with full text separately provided to HTCC.

Commenter	Comment Period	Cited Evidence
	April 26 – May 10	
Patient, relative, and citizen	4	0
Legislator and public official	0	0
Physician and health care professional	8	0
Industry and Manufacturer	0	0
Professional Society and Advocacy Organization	3	1

All Total = 15

Agency Comments:

Replace more general term “nerve blocks” with the more specific term “medial branch blocks” to reduce policy uncertainty.

Request implementation clarification or modification on coverage condition language related to sacroiliac joint injection:

- The clinical committee discussion centered on a belief that better outcomes are achieved because of better precision when injections are delivered under guidance. The committee discussed that this is generally standard practice and that it is believed to enhance quality. This correlation was not reviewed specifically in the literature, and thus the evidence basis is unclear. However, the primary agency concern is the general inclusion of both fluoroscopic and CT Guidance.
- Agencies will implement this language by routine authorization of fluoroscopic guidance and authorization of CT Guidance only when fluoroscopic guidance is contraindicated or is incapable of providing the necessary level of imaging detail.

Comments with Evidence:

Professional Society and Advocacy Organization Comments

American Society of Interventional Pain Physicians (ASIPP)

- Requested modification of the decision as follows: coverage for therapeutic facet joint injections, either intraarticular or medial branch blocks; expansion of epidural indications for spinal stenosis, post surgery syndrome, and discogenic pain after facet joint pain as well as sacroiliac joint pain has been ruled out.

Comments without Evidence:

Patient, relative, and citizen comments

Bradley Smith, K. Master, Patsy Podeseck, Ricky Walsh,

- Request coverage continuation for spinal injections.
- Strongly endorse spinal injections; can't afford out-of-pocket for long term disability; disappointed that no longer covered; the procedure is less expensive than surgery and less invasive.

Physician and Health Care Professional Comments

Alison Stout, DO, Director of Spine and Musculoskeletal Services, Department of Rehabilitation Medicine, Veterans Health Services

- Requested clarification that all of the research presented and materials reviewed was regarding spinal injections for therapeutic purposes (no materials were presented nor discussed about spinal injections for diagnostic purposes). Requested change of term “nerve block injections” has been used in place of the more scientific terms “medial branch nerve block injections”; therefore, requests that the terms be corrected.

Paul Dreyfuss, MD

- Requested clarification that the decision was not to exclude “nerve block injections” from coverage but to exclude only therapeutic medial branch blocks. Requested change of the term “nerve blocks injections” is far too generic a term and could be misrepresented to include diagnostic nerve block procedures of many different types. Indicated that epidural steroid injections are not just for frank radiculopathy but for radicular pain.

Bing Manawadu, MD; Timothy Baldwin, MD; Michael Carpenter, MD; David Dickerman, MD; John Groner, MD; Ghassan Nemri, MD and Matthew Peterson, MD

- Requested revisions to decision to include: conservative treatment algorithm for spinal pain with or without radicular symptoms in the absence of sensory or motor deficits shall include spinal therapy prior to corrective surgical treatment; suggest the word “therapeutic” be inserted before epidural injections and ultrasound is added as an imaging modality for Sacroiliac joint injections.

Steven R. Pollei, MD, Medical Director, Center for Diagnostic Imaging (CDI)

- Disagree with conclusion and decision regarding spinal injection procedures. Further work should be done to assure that patients are not restricted from access to injection procedures when the only alternatives may be expensive and risky spine surgery or, possibly even riskier, long term use of narcotic substances for pain control.

Jason Attaman, MD

- Requested that the term “nerve block injections” be replaced with “therapeutic medial branch blocks”.

Andrew Cole, MD; Doug Burns, MD

- Requested revision to document: non-coverage only for therapeutic Medical Branch Blocks; clarify decisions only cover therapeutic injections; Epidural steroid injections are not just for radiculopathy but also for radicular pain. Radiculopathy requires a neurologic deficit to be present, radicular pain does not.

Professional Society and Advocacy Organization Comments

International Spine Intervention Society (ISIS), Way Yin, MD, President

- Concerned that the draft findings & decision does not differentiate between diagnostic and therapeutic medial branch blocks and that vascular puncture should not be listed under major complications, but rather under minor complications.

North American Spine Society (NASS)

- Requested for clarification or added language to the following: regarding the documentation of efficacy and limiting the number of injections to three in a six month period is a reasonable cost containment policy. Currently, the way the language is stated refers to a body region, rather than the whole body. Patients may develop a cervical radiculopathy, which if successfully treated, and at some point develop a lumbar radiculopathy. That obviously would need to be treated separately; therefore, having this clarified may avoid unfair and unnecessary denials of care. Lastly, clarification is requested that repeat sacroiliac injections will be allowed if the patients obtains adequate pain relief and functional improvement for a reasonable timeframe.

Actual Timeline		Total Public Comment Days
Preliminary recommendations published	October 27, 2009	
Public comments due:	November 10, 2009	15 days
Selected set of topics published:	December 8, 2009	
Public comments due:	January 11, 2010	35 days
Draft Key Questions Published:	July 20, 2010	
Public comments due:	August 3, 2010	15 days
Key Questions Finalized:		
Draft report due:	November 5, 2010	
Draft report published:	November 10, 2010	
Public Comments due:	November 24, 2010	15 days
Final report due:	December 8, 2010	
Final report published:	December 17, 2010	
Public meeting Date:	March 18, 2011	
Findings & Decision Published	April 26, 2011	
Public Comments due:	May 10, 2011	15 days

HCA/HTCC Administrator
Washington State Health Care Authority
P.O. Box 42682
Olympia, WA 98504-2682

May 10, 2011

Re: Spinal Injections Draft Report
Meeting Date 3/18/2011

I am concerned with several discrepancies/ambiguities between the Findings and Coverage Decision Draft Report and the discussion/voting held by the HTCC on 3/18/11. I was in attendance, and would like to make some clarifications that I feel are necessary.

First and foremost, it should be clarified that all of the research presented by SPECTRUM, the research vendor, and all of the material reviewed by the HTCC, was regarding spinal injections for **therapeutic** purposes. There was absolutely no material presented nor discussion about spinal injections for **diagnostic** purposes which should be clearly described by this report. Coverage for diagnostic spinal injections cannot be extrapolated from evidence for therapeutic procedures, and if a coverage decision is to be made it should be from review of the pertinent evidence. The report should clearly state that coverage determination is for therapeutic spinal injections.

Secondly, it appears that the term "nerve block injections" has been used in place of the more scientific term, "medial branch nerve block injections." I agree that the HTCC decided on **non-coverage of the medial branch nerve block injections for therapeutic** purposes. The term "Nerve Block," however, is overly vague, and can refer to any injection of a nerve and can even be used to describe Epidural Injections (which are covered in the Coverage Decision Report). This vague nomenclature needs to be corrected. Again, as above, the use of medial branch nerve block injections for **diagnostic** purposes was not assessed in the research review nor at the meeting and a coverage decision cannot be made.

Therefore, from my understanding of the proceedings at the meeting, the opening sentence on the report, "Nerve Block Injections, Intradiscal Injections and Facet Injections are **not a covered benefit,**" should read, "Medial Branch nerve block injections, intradiscal injections and facet injections for therapeutic purposes **are not a covered benefit.** "

Lastly, the coverage of cervical-thoracic and lumbar epidural injections states in the Coverage Determination that "covered benefit for the treatment of ...and associated radiculopathy." This is in contrast to the description following it, below, in "HTCC

Reimbursement Determination" that states it is covered "For treatment of radicular pain." The diagnosis of radiculopathy is medically distinct from radicular pain. It should be made clear in the "Coverage Determination" section that radicular pain or "radiculitis" is the required condition as was determined by the HTCC.

Thank you for reviewing my concerns.

Sincerely,

Alison Stout, D.O.
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Department of Rehabilitation Medicine
Veterans Health Services, Puget Sound
Acting Assistant Professor, University of Washington

American Society of Interventional Pain Physicians

" The Voice of Interventional Pain Management "

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March 29, 2011

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RE: Health Technology Assessment of Spinal Injections

Ms. Santoyo, Ms. Hole-Curry, and Ms. Dennis:

On behalf of the American Society of Interventional Pain Physicians (ASIPP), and the Washington State Society of Interventional Pain Physicians (WASIPP), we would like to thank you for providing us an opportunity to comment on spinal injections, convening a final meeting on 3/18/2011, and providing a 2 week notice period. We are also grateful for the open process of consideration of these important treatments. We feel the importance of these issues is emphasized by the number of professional societies who have voiced concern, such as the International Spine Intervention Society. In addition, these decisions will have international implications, as evidenced by the world-renowned experts who have voiced concern, including the distinguished Dr. Bogduk from Australia. As you are well aware, we have sent you letters on January 11, 2010 and November 24, 2010, and Dr. Manchikanti also has provided peer review for Spectrum Research voluntarily with no remuneration (1). However, Spectrum Research ignored all the comments. We believe interventional pain management has been well represented and appropriate opportunities have been provided, however, we would like to comment and request your consideration for coverage or modification of the following:

1. Coverage for therapeutic facet joint injections, either intraarticular or medial branch blocks
2. Expansion of epidural indications for spinal stenosis, post surgery syndrome, and discogenic pain after facet joint pain as well as sacroiliac joint pain has been ruled out

We understand the concern of HTA with regards to overuse, fraud, and abuse. We have expressed our concern and also have published multiple manuscripts on controlling fraud and abuse, not only with respect to interventional techniques, but also with opioids and urine drug testing (2-8). Our position is similar to OIG's position. However, we believe that appropriate health care may be provided cost effectively with proper regulations. Spectrum Research has utilized only one physician, namely Chou, who stated that there was no conflict of interest on his part, however, as you know looking at the records of the American Pain Society it appears that he has received over \$1.2 million from the American Pain Society to prepare guidelines under his direction. Further, in a recent manuscript published in the *Annals of Internal Medicine*, potential conflicts of interests included a consulting fee or honorarium from multiple insurers such as Well Point, Blue Cross Blue Shield Association, Palladian Health, and Consumers Union, including payment for preparing a manuscript for the American College of Physicians. It is rather surprising that just 7 months ago Dr. Chou stated there was nothing to disclose during ASIPP's Annual Meeting. Further, Spectrum Research has not taken into consideration the response we have written to his critiques and allegations (9-12). Apart from Spectrum and Chou, there is justification for the above request based on significant evidence for therapeutic medial branch blocks and epidural injections in conditions other than disc herniation and radiculitis. However, for sacroiliac joint injections, evidence is low; based on a lack of research and consensus approach, the procedure may be covered.

1.0 FACET JOINT INJECTIONS

1.1 Diagnostic Blocks

In contrast to the mixed picture provided by history, physical examination, imaging, and nerve conduction studies in non-radicular pain, controlled diagnostic blocks have been shown to determine the cause of pain in as many as 85% of patients, in contrast to 15% of patients with other available techniques.

The role of controlled diagnostic blocks in the diagnosis of facet joint pain has been described in multiple publications (13-16) It has been established that the diagnosis can only be furnished appropriately with 80% pain relief with concordant duration based on local anesthetic injected with comparative local anesthetic blocks or placebo controlled blocks with the ability to perform previously painful movements. The ASIPP guidelines (17), published in July/August 2009, utilized a comprehensive review process. Based on the systematic review by Datta et al (16) utilizing 7 studies meeting inclusion criteria with 80% pain relief and the ability to perform previously painful movements with controlled diagnostic blocks of lumbar facet joint nerves, showed evidence of Level I or II-1 based on the United States Preventive Services Task Force (USPSTF) criteria (18). Similarly Falco et al (15), utilizing similar criteria of 80% relief with controlled diagnostic blocks with ability to perform previously painful movements, utilized 9 studies meeting inclusion criteria and showed Level I or II-1 evidence based on the USPSTF criteria. Atluri et al (14), utilizing 3 studies, showed Level II-1 evidence based on USPSTF criteria.

The validity of facet joint nerve blocks in the diagnosis of facet joint pain has been established with multiple variables including with establishment of long-term follow-up (19,20) influence of sedation (21-24), psychological variables (25,26) opioid intake (27) and post-surgery (28,29).

Further, Rubinstein and van Tulder (30), experts in evidence-based medicine and publishers of many Cochrane reviews, in a best-evidence review of diagnostic procedures for spinal pain concluded that there is strong evidence for the diagnostic accuracy of facet joint nerve blocks.

In summary, the 3 systematic reviews showed a prevalence of lumbar facet joint pain in 21% to 40% in the heterogenous population with chronic low back pain, and 16% in post-lumbar surgery syndrome with an overall prevalence of 31% (16), 36% to 67% in patients with chronic neck pain with an average prevalence of 49% (15), and 34% to 42% in patients with chronic thoracic pain (14). These studies also showed false-positive rates of 17% to 49% with an overall false-positive rate of 30% in the lumbar spine (16), 27% to 63% in the cervical spine with an average of 49% (15) and 42% to 55% in the thoracic spine (14).

1.2 Therapeutic Medial Branch Blocks

An evidence assessment for medial branch blocks was recently a part of the ASIPP guidelines, with 3 systematic reviews (14-17) evaluating the effectiveness of therapeutic facet joint nerve blocks (Table 1). The previous systematic reviews by ACOEM (31), Chou and Huffman (32), and Staal et al (33) are not only outdated, but also have failed to utilize appropriate criteria for meeting inclusion (9,10,34-37). Thus, the ASIPP guidelines and the 3 systematic reviews are superior because of their evidence and utilization of sound methodology. Further, additional evidence, which has been available since the publication of these guidelines and systematic reviews, also confirms the analysis with 2-year follow-up (38-43).

Table 1. Results of randomized trials of effectiveness of cervical, thoracic, and lumbar medial branch blocks.

Study	Study Characteristics	No. of Patients	Long-term Relief			Results	
			6 mos.	12 mos.	24 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
CERVICAL							
Manchikanti et al 2008 (41), 2010 (38)	RA, DB	Group I = 60 Group II = 60	87% vs 95%	85% vs 92%	85% vs. 93%	P	P
THORACIC							
Manchikanti et al 2008 (42), 2010 (40)	RA, DB	Group I - no steroid=50 Group II - steroid=50	94% vs 94%	90% vs 90%	NA	P	P
LUMBAR							
Manchikanti et al 2008 (43), 2010 (39)	RA, DB	Group I - no steroid = 60 Group II - steroid = 60	83% vs 93%	82% vs 85%	85% vs. 90%	P	P

RA = randomized; DB = Double-blind; O = observational; vs = versus; P = positive; N = negative

Adapted and Modified From:

Falco FJE et al. Systematic review of diagnostic utility and therapeutic effectiveness of cervical facet joint interventions. *Pain Physician* 2009; 12:323-344 (15).

Atluri S et al. Systematic review of diagnostic utility and therapeutic effectiveness of thoracic facet joint interventions. *Pain Physician* 2008; 11:611-629 (14).

Datta S et al. Systematic assessment of diagnostic accuracy and therapeutic utility of lumbar facet joint interventions. *Pain Physician* 2009; 12:437-460 (16).

It is essential for methodologists and clinicians to accurately follow the requirements of evidence-based medicine in conducting systematic reviews of diagnostic accuracy studies. The 3 reviews by ACOEM (31), Chou et al (32), and Staal et al (33) were deficient in this regard. The systematic reviews and ASIPP guidelines utilized 4 randomized trials evaluating the effectiveness of facet joint nerve blocks and meeting the inclusion criteria utilizing active control design. These studies are referred to as non-inferiority or equivalence trials, consequently, they lack a placebo. However, active control designs show the existence of effect and compare the therapies – comparative effectiveness, which is promoted in the United States.

These studies also were conducted based on consolidated standards of reporting trials (CONSORT) criteria (44). All the studies except the earliest one (45) were double-blind, randomized, and controlled trials with inclusion of outcome assessments with numeric pain scores, Oswestry or Neck Pain Disability Index, opioid intake, and work status reported at baseline, 3 months, 6 months, 12 months, 18 months, and 2 years. In these studies, they considered significant relief as 50% or greater and significant functional status improvement as 40% or more – which are robust measures robust measures. The

inclusion criteria involved confirmation of the existence of facet joint pain based on 80% relief with controlled local anesthetic blocks. All the studies showed positive results with 82% to 93% of the patients showing positive results on a long-term basis of one-year for thoracic facet joint blocks and 2 years for cervical and lumbar facet joint nerve blocks (38-40). As touted by many, the limitations of these studies include the lack of placebo, a non-academic setting, and single-center studies. The same authors also published prospective studies that have been mentioned before; however, results of randomized studies were shown to be superior.

Manchikanti et al (38,41) in the publication of cervical medial branch blocks at one-year follow-up of a randomized, double-blind, controlled trial evaluated a total of 120 patients with 60 patients in each of the local anesthetic and steroid groups. All of the patients met the diagnostic criteria of cervical facet joint pain by means of comparative, controlled diagnostic blocks, as well as the inclusion criteria. The results showed significant pain relief (> 50%) and functional status improvement was observed at 6 months, 12 months, and 24 months in 80% to 93% of the patients. The average number of treatments per year was 3.5 ± 1.0 in the non-steroid group and 3.4 ± 0.9 in the steroid group. Duration of average pain relief with each procedure was 14 to 16 weeks. Significant relief and functional improvement was reported for 46 to 48 weeks in a one-year period. The average number of treatments for 2 years was 5.7. The duration of average relief with each procedure was 17 to 19 weeks on average in both groups. Significant improvement of pain and function was demonstrated for 83 to 89 weeks over a period of 2 years.

Manchikanti et al (40) in a one-year follow-up of thoracic medial branch blocks in the management of chronic thoracic pain included a total of 100 patients with 50 patients in each of the local anesthetic and steroid groups. In Group I and Group II 90% of participants showed significant pain relief and functional improvement at 12 months. The majority of the participants experienced significant pain relief of 47.2 ± 10.1 weeks in Group I and 46.3 ± 8.4 weeks in Group II, requiring approximately 3.5 treatments per year with an average relief of 15.8 ± 10.5 weeks in Group I and 13.6 ± 3.6 weeks in Group II per treatment.

Manchikanti et al (39,43) in a randomized, double-blind, controlled trial of lumbar facet joint nerve blocks in managing chronic facet joint pain included 60 patients in Group I with local anesthetic and 60 patients in Group II with local anesthetic and steroid. The results utilizing multiple outcome measures such as numeric pain scores and Oswestry Disability Index (ODI) showed significant pain relief of greater than 50% and functional status improvement of at least 40% in 82% in Group I and 85% in Group II. The results of the same study were published with a 2-year follow-up (39) which illustrated the sustainability of the results showing significant improvement observed in 85% of the patients in Group I and 90% in Group II with a total of 5 to 6 treatments, an average relief of 19 weeks per treatment, and patients experiencing significant pain relief for 82 to 84 weeks out of 104 weeks. Consequently, this is the longest follow-up study of a controlled, randomized, double blind trial for therapeutic lumbar facet joint nerve blocks using strict criteria.

The cost-effectiveness of lumbar facet joint nerve blocks was also evaluated (45), with one-year improvement of quality of life at \$3,461 which was superior to multiple other treatments.

Consequently, the 3 systematic reviews concluded that the indicated level of evidence, based on USPSTF criteria (18) for lumbar, thoracic, and cervical facet joint nerve blocks, is Level II-1 or II-2. They also concluded, based on Guyatt et al's criteria (46), the recommendation as strong (1B or 1C) for the use of therapeutic cervical, thoracic, and lumbar facet joint nerve blocks to provide both short-term and long-term relief in the treatment of chronic facet joint pain.

Thus, we believe that facet joint nerve block effectiveness was not appropriately evaluated. In fact, the evidence is superior for therapeutic medial branch blocks compared to radiofrequency neurotomy either in the cervical or lumbar spine, and while there are no studies available for radiofrequency neurotomy in the thoracic spine, even though, each procedure has its own indications and patient preference. Cost utility analysis will be the same for both procedures and probably lower in the cervical spine for medial branch blocks because in the cervical spine, if a patient is suffering with bilateral pain it can be performed only one side each time resulting in double neurotomy procedures which will increase the cost.

Further, multiple Medicare carriers, including Noridian, also have approved these treatments. According to Noridian guidelines, the initial phase includes 2 diagnostic interventions once a patient has been proven to have facet joint pain judged by at least 80% relief with the ability to perform previously painful movements with concordant pain relief with 2 local anesthetics. A patient is allowed 4 therapeutic facet joint blocks per year after that. The rolling calendar year is 12 months, when the first therapeutic block took place; i.e., if the first therapeutic nerve block was performed in February 2011, the rolling calendar year would end in February 2012 (47).

2.0 EPIDURAL INJECTIONS

Access to the epidural space is available by caudal, interlaminar, and transforaminal approaches (3). Substantial differences in technique and outcomes have been described among the 3 approaches. Thus, due to the inherent variations, differences, advantages, and disadvantages applicable to each technique (including the effectiveness and outcomes), of caudal epidural injections, interlaminar epidural injections (cervical, thoracic, and lumbar epidural injections), and transforaminal epidural injections (lumbosacral) are considered as separate entities.

There have been multiple systematic reviews performed evaluating the role of various types of epidural injections in multiple regions and for multiple conditions (48-51). The evidence has been fair to good for lumbar transforaminal and caudal epidurals for patients with disc herniation and radiculitis in the lumbar spine, and cervical interlaminar epidural injections in the cervical spine. The emerging literature also illustrates positive evidence for lumbar interlaminar epidural injections, and thoracic interlaminar epidural injections for disc herniation. You have already approved this, thus we are very grateful for your approval.

However, what has not been approved is post lumbar surgery syndrome, spinal stenosis, and discogenic pain. Thus far, caudal epidurals have provided fair to good evidence for lumbar spinal stenosis and post lumbar surgery syndrome. Tables 2 and 3 illustrate the results.

Table 2. Results of randomized trials in managing low back pain of post-surgery syndrome with caudal epidural injections.

Study	Study Characteristics	Participants	Pain Relief			Results	
			3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
Manchikanti et al 2008 (52)*, 2010 (53)	RA, DB	Group I - LA = 70 Group II - LA + steroid = 70	66% vs 69%	60% versus 66%	56% vs 61%	P	P
Revel et al 1996 (54)	RA	Forceful injection = 29 Regular = 31	NA	49% vs 19%	NA	P	P
Hesla and Breivik 1979 (55)	RA, DB	69 patients: crossover design	77% vs 29%	59% vs 25%	59% vs 25%	P	P

*Indicates use of fluoroscopy

RA = randomized; DB = double blind; NA = not available; vs = versus; P = positive; N = negative; LA = local anesthetic

Adapted and modified from Conn A, et al. Systematic review of caudal epidural injections in the management of chronic low back pain. *Pain Physician* 2009; 12:109-135 (48).

Table 3. Results of effectiveness in evaluation in managing spinal stenosis.

Study	Study Characteristics	Participants	Pain Relief			Results	
			3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
Manchikanti et al 2008 (56)*, 2010 (57)	RA, DB	Group I - LA = 50 Group II - LA + steroid = 50	49% vs 58%	50% vs 54%	46% to 48%	P	P
Ciocon et al 1994 (58)	O	30	SI	SI	NA	P	NA
Botwin et al 2007 (59) *	O	34	65%	62%	54%	P	P

*Indicates use of fluoroscopy

RA = randomized; DB = double blind; O = observational; NA = not available; SI = significant improvement; vs = versus; P = positive; N = negative; LA = local anesthetic

Adapted and modified from Conn, A et al. Systematic review of caudal epidural injections in the management of chronic low back pain. *Pain Physician* 2009; 12:109-135 (48).

As you well know, spinal stenosis can produce nerve root compression and cause radiculitis, but at the same time it may not do so. Further, post lumbar surgery syndrome also can produce a variety of spine related problems, including recurrent disc herniation, radiculitis, and epidural fibrosis. These should be included in the approved procedures.

Discogenic pain without facet joint pain and without disc herniation or radiculitis also has been shown to be responsive to caudal epidural injections, lumbar interlaminar epidural injections, and cervical epidural injections as shown in Table 4.

Table 4. Results of randomized and observational studies of effectiveness of caudal epidural steroid injections in managing discogenic pain.

Study	Study Characteristics	Participants	Pain Relief			Results	
			3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
CAUDAL							
Manchikanti et al 2008 (60), 2011 (61)	RA, DB	Group I - LA = 60 Group II - LA + steroid = 60	87% versus 88%	89% vs 93%	84% versus 85%	P	P
Manchikanti et al 2001 (62)*	O	70	95%	85%	61% to 73%	P	P
Manchikanti et al 2002 (63) *	O	62	86%	60%	NA	P	NA
LUMBAR INTERLAMINAR							
Manchikanti et al 2010 (64)	RA, DB	Group I - LA = 35 Group II - LA + steroid = 35	80% vs 83%	69%	60% v 71%	P	P
CERVICAL INTERLAMINAR							
Manchikanti e al 2010 (65)	RA, DB	Group I - LA = 35 Group II - LA + steroid = 35	77% vs 86%	80% vs 86%	80%	P	P

*Indicates use of fluoroscopy

RA = randomized; DB = double blind; O = observational; NA = not available; P = positive; N = negative; LA = local anesthetic; vs = versus

Adapted and modified from Conn A, et al. Systematic review of caudal epidural injections in the management of chronic low back pain. *Pain Physician* 2009; 12:109-135 (48).

Further, epidural injections, as you have seen and approved, are approved by multiple insurers. In fact, a majority of epidural injections are performed in patients without demonstrable radiculitis or disc herniation (2-4). Thus, this will be an ideal treatment to be approved.

Appropriate frequency for any injection therapy which is not neurolytic is 2 treatments in the beginning with proper documentation of response followed by 4 therapeutic injections per region. The rolling calendar year is 12 months, when the first therapeutic block took place; i.e., if the first therapeutic nerve block was performed in February 2011, the rolling calendar year would end in February 2012.

3.0 SACROILIAC JOINT INJECTIONS

Thank you for approving sacroiliac joint injections. On the issue of sacroiliac joint injections, there is no significant evidence with regards to the therapeutic effectiveness of sacroiliac joint interventions as rightly shown in your evaluation and all other guidelines and systematic reviews. In a systematic review, Rupert et al (66) provided the latest evidence with prevalence of sacroiliac joint pain to range between 10% and 38% with a false-positive rate of 20% to 54%. The evidence was Level II-3 or limited for therapeutic interventions with a weak recommendation.

Even though the diagnostic evidence is moderate, nevertheless patients still suffer with sacroiliac joint arthritis. The procedure should be allowed with appropriate diagnostic criteria with 2 diagnostic blocks and 4 therapeutic blocks per year in a similar fashion as described for therapeutic medial branch blocks.

Thank you in advance for your consideration of ASIPP, WASIPP, and our comments. We are hopeful that this information will provide you with a summary of the current evidence for pending spinal injections based on evidence-based medicine, comparative effectiveness research, cost effectiveness, and above all, patient access to high quality health care.

If you have any further questions, please feel free to contact us.



Laxmaiah Manchikanti, MD

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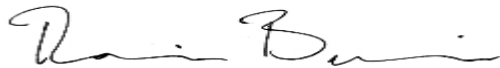
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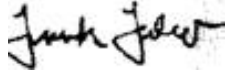
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REFERENCES

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To Whom it May Concern,

I am writing to you to comment on the Draft HTCC Findings and Coverage Decision document that was released by the HTA and open for public comment until May 10, 2011.

I was present at the hearing and am stunned by the discrepancies between the decisions and this draft document.

In particular:

The decision was NOT to exclude "Nerve Block Injections" from coverage but to exclude ONLY THERAPEUTIC Medical Branch Blocks;

The decisions ONLY covers therapeutic injections and NOT diagnostic blocks. Diagnostic blocks are critical to proper patient care;

Epidural steroid injections are NOT just for radiculopathy but also for radicular pain. Radiculopathy requires a neurologic deficit to be present, radicular pain does not.

I ask that you amend this document to reflect what was agreed to in order to maintain the integrity of this process.

Sincerely,

Andrew J. Cole, MD

Andrew J. Cole, M.D.

andrewjcole@comcast.net

Work Phone: 425-451-2272

Cell Phone: 425-830-5354

Health Technology Clinical Committee review of the evidence and recommendations for coverage of spinal injections.

Dear commissioners,

We are interventional Pain Physicians practicing in Tri-Cities, Washington and respectfully submit the following observations and recommendations before the final decisions are made.

1. Conservative treatment algorithm for spinal pain with or without radicular symptoms in the absence of sensory or motor deficits shall include spinal therapy prior to corrective surgical treatment.

2. Although this document distinguishes between therapeutic and diagnostic blocks they share the same CPT code which may lead to audit discrepancies. We suggest the word therapeutic be inserted before epidural injections:

No more than 2 *therapeutic* epidural injections may be performed unless clinically meaningful improvement in pain and function is documented.

A maximum of 3 *therapeutic* injections may be performed in 6 months (per body area: cervical, thoracic, or lumbar)

3. Ultra sound is added as an imaging modality for Sacroiliac joint injections.

Injections must be performed with fluoroscopic or CT -guidance or *Ultra-sound*.

Timothy Baldwin, MD



Michael Carpenter, MD

Support and agreement via Telephone conference

David Dickerman, MD

Support and agreement via Telephone conference

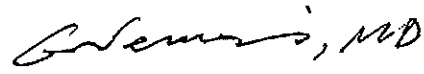
John Groner, MD



Bing Manawadu, MD., Ph.D



Ghassan Nemri, MD



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Timothy Baldwin, MD

Michael Carpenter, MD

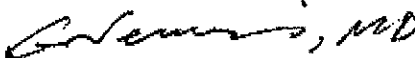
David Dickerman, MD

John Groner, MD

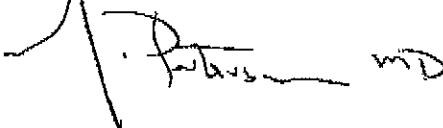
Bing Manawadu, MD., Ph.D



Ghassan Nemri, MD



Matthew Peterson, MD



Tuesday, Mar. 29, 2011

1 Comment

Spinal injections

I am in shock after reading that the state of Washington is considering not funding spinal injections. This procedure has worked for me for the last five years. Is it better to take oxycodone or oxycontin every day, or have an epidural once or twice a year?

Nerve pain is the worst pain of all. Fortunately I have private insurance that pays for treatment, I can't imagine the suffering that patients with state health care will endure. Someone in our government is truly ignorant and heartless. This is only the beginning of public health care. God help us.

Marie Schrimpe, Kennewick

Spinal injections - Letters to the Editor | Tri-City Herald : Mid-Columbia news

Page 1 of 1

Wednesday, Mar. 30, 2011

0 Comments

Spinal injections

I am writing in reference to the recent report that the state may stop paying for patients' spinal injections. To me it was very important that I received the injections, and I know of other patients who are in need of them. Like everything else, the state wants to make cuts where it should not.

Dr. Bin Manawadu and Dr. Ghassan Nemri know what they are doing when it comes to spinal injections. They have both given me injections. To send patients out of the state would only hurt our doctors here that know their specialty.

EARLEYNE BAZE, Kennewick

Wrong priorities - Letters to the Editor | Tri-City Herald : Mid-Columbia news

Page 1 of 1

Wednesday, Mar. 30, 2011

0 comments

Wrong priorities

I am a senior citizen who is almost 90 years old, and I resent the state of Washington even thinking of stopping payment to the doctors for spinal injections. I have had a back problem (as many seniors do) for quite a few years. This treatment has helped me immeasurably.

Instead of cutting programs that help people (seniors and younger), the state should be spending that energy going after the drug cartels that are so rampant in this state.

ELAINE WHITEFORD, Pasco

Friday, Mar. 18, 2011

0 comments

State may stop funding for spinal injections

By Michelle Dupler, Herald staff writer

RICHLAND — A little-known state committee today will consider whether state health care programs should continue to pay for spinal injection treatments for back and neck pain.

But a Richland pain medicine specialist worries that patients will be driven either to narcotic pain medicines or expensive surgeries if the state stops paying for the injections.

He also worries the state will set a precedent that private insurance companies soon will follow.

"First, they will deny payment," said Dr. Bing Manawadu. "They won't fund it. Soon private payers will follow the government-mandated payment policies. It will deny access to the patients of Washington. Patients would have to pay cash or leave the state (for treatment)."

The treatment has been under review by the Health Technology Assessment Program since late 2009. The program identifies health care technologies to review for safety and effectiveness, essentially making sure the state and patients are getting the best bang for their buck.

Leah Hole-Curry, assessment program manager, said the program was created by the Legislature and is directed by statute to evaluate medical technologies for safety, efficacy and cost-effectiveness.

The program evaluates about a dozen technologies each year, which involves hiring an independent third-party research group to collect evidence about a given technology and then provide a report to the program.

The report includes information from medical literature as well as whatever public comments are submitted by doctors, patients or the general public, Hole-Curry said.

The researchers don't make any recommendations about whether the state should continue paying for a type of treatment. That decision is made by an 11-member committee made up of health care professionals, she said.

Also being considered by the committee today is the use of glucose testing in children.

The committee has made decisions on 21 technologies to date.

According to program records, a technology was deemed to have some benefit and coverage was supported in 11 cases. But in nine cases, the committee decided a technology did not provide a benefit and opted not to cover it.

Only one technology was shown to be unsafe or ineffective.

Some of the technologies or procedures the committee decided not to cover include bariatric surgery for minors, virtual colonoscopies and arthroscopic knee surgery.

The committee found some merit to technologies such as breast MRIs, cardiac stents, computer-navigated knee surgery and artificial disc replacements.

The report on spinal injections, prepared by a company called Spectrum Research, found from a review of medical literature that there was little or no benefit to patients from the use of spinal injections, such as epidurals, to manage back and neck pain.

But Manawadu said the report is flawed and that he's seen first-hand what the injections have done for hundreds of patients.

"They did not ask people like myself in the trenches taking care of these problems," he said. "They didn't want to listen."

Manawadu said the term "spinal injections" covers a number of procedures that involve injecting chemicals into the spine or nerve roots.

He said they are relatively noninvasive and allow a patient to go home the same day, compared to a back surgery that would have a patient in the hospital for days and take months of recovery time.

"(Injections) are effective in controlling pain and various conditions that affect the spine," he said.

The only alternatives are opiates -- which can have long-term health effects -- or surgery.

He said a spinal injection typically costs less than \$1,000, but surgery costs tens of thousands, depending on the procedure.

"My bottom line on this is it will actually increase the cost," he said. "This is a short-sighted thing. It will save money in the short term, but in the long-term it will lead to increased costs and increased human suffering."

If the committee makes a decision today, a draft of the decision will become available for comment. A final decision would be made at the committee's next quarterly meeting.

5207 Manor Drive
Yakima, WA 98901
May 07, 2011

Health Technology Assessment Program
P.O. Box 42712
Olympia, WA 98504-2712

RE: Spinal injection insurance review

Dear Health Technology Assessment representative:

I understand that spinal injections are currently under insurance justification review. I have been a lumbar/sympathetic injection patient since 2006 and received multiple week-long nerve block series and both trigger point and tender point injections, and would like to share that for me, nerve-block injections provide critical longer-term pain suppression.

I have several upper and lower-body pain generating orthopaedic and neural chronic medical conditions, including sacroiliac joint disease, multiple vertebral conditions, complex regional pain syndrome in my left leg, and causalgia of the lower limbs, and those cause strong, sharp pain in the lower spine and back; strong, deep, hip-area burning and pain; stinging thigh pain; strong leg pain; pervasive deep pain; and hard-to-tolerate deep, aggressive, and burning complex regional pain syndrome pain. Spinal nerve-block injections are the best comprehensive pain treatment I receive. They have even minimized some pain, such as the CRPS pain, almost to imperceptible.

Loss of nerve blocks would either require stronger narcotic prescriptions, although federal prescription monitoring is an active pressure on the medical community, or remaining with weaker prescriptions or lower daily medication totals and accepting dosage rationing and more pain. However, less pain management promotes health deterioration, which in turn causes more pain. As a result, the eventual consequence of a spinal injection loss, from my perspective, would be twofold: increased medical costs in multiple ways in chronic-pain patient care, and more terminal chronic pain cases.

The committee has heard from some for whom these injections were not effective, but it is imperative to review enough cross-sectional study. Dr. Bing Manawadu of Richland does my injections, and my wife, who is a nurse and is allowed to observe my procedures, knows what she is watching on the fluoroscope and tells me Dr. Manawadu is precise. I would suggest asking Dr. Manawadu's office for patient contacts who would speak to his injections, spinal and otherwise. I understand Dr. Quave in Yakima does well at spinal injections, also, and I have learned that Swedish Hospital in Seattle has a pain specialist now. Swedish is an excellent hospital; I had leg surgery there in 1995. Has the HTA program surveyed regular patients of successful clinics?

It is true that spinal injections do not help everyone. I personally know of three such people, and my wife knows others, but I would ask whether that is the procedure, or the doctor and equipment. Was a fluoroscope used?

HCA spinal injection insurance cancellation would cause a logistical nightmare for those who would have to replace it during a time of health duress, but that needs no explanation. The key fact is that continuing them would help both State of Washington health care and the patient; with proper equipment and medical skill, these injections make a difference. Spinal injections are a necessity for me, and I have assessed whether I can afford them out-of-pocket from long-term disability benefits. I cannot. I sincerely appeal to you for a studied Health Technology Assessment Program decision.

Thank you for your time.

Sincerely,

A handwritten signature in cursive script that reads "Bradley D. Smith".

Bradley D. Smith

CENTER FOR
DIAGNOSTIC IMAGING



April 14, 2011

Jeff Thompson, M.D., MPH
Chief Medical Officer
Health Technology Assessment Program
676 Woodland Square Loop SE
P.O. Box 42712
Olympia, WA 98504-2712

Sent Electronically

Dear Dr. Thompson:

I am the medical director of two diagnostic imaging clinics in Federal Way and Lakewood and have an expertise in several types of image-guided diagnostic and therapeutic interventional spine procedures. Under the CDI umbrella, our centers are part of an eight center partnership throughout Puget Sound as well as a broader network of radiology practices in seven other states. CDI is known nationally for our commitment to quality through sub-specialization and for patient service. We have pioneered many spine interventional techniques.

We have reviewed both the March 10, 2011, Spinal Injections report and recommendations as well as the earlier comments and responses regarding the draft report.

We have concerns with some of the conclusions reached in your final report, most especially the amount of savings you believe have resulted from your collection of recommendations. We hope and expect the HTA Program to be held accountable to verify these savings.

Specifically regarding spine injection procedures, further and continuous work should be done to assure that patients are not restricted from access to injection procedures when the only alternatives may be expensive and risky spine surgery or, possibly even riskier, long-term use of narcotic substances for pain control.

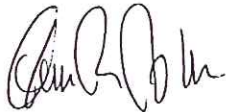
Letter to HTA from Dr. Pollei
April 14, 2011
Page 2

Furthermore, the cultural shift that has our patients/citizens longing for transparency-in-process should create an urgency for all state-sponsored entities to respond. Allow me to encourage you to revamp your reassessment plans so that Washington state physicians, who are experienced in the procedures of concern, participate in the sifting and interpretation of the available research. Additionally, your group should consider surveying the efforts undertaken by commercial payers and purchasers across the country. Some of these companies are also concerned with the efficacy of these procedures, as well as many health care services. These entities have significant data that may be richer in information than what can be generated from the Medicare claims data set or from an academic institution conducting a clinical trial.

While I appreciate the extensive academic exercise you have undertaken, the practice of medicine must continue to be one that is patient-centric. To do this requires continuous improvement and innovation.

We look forward to hearing of your continued efforts to assure that all patients in Washington receive prompt, appropriate treatment.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Steven R. Pollei". The signature is fluid and cursive, with the first name being the most prominent.

Steven R. Pollei, M.D.

c: Dr. Dean Martz, President, WSMA

To Whom it May Concern,

I am writing to you to comment on the Draft HTCC Findings and Coverage Decision document regarding Spinal Injections that was released by the HTA and open for public comment until May 10, 2011.

I was present at the HTCC hearing and wish to add some clarification to what was released in the draft decision document.

Specifically:

The decision was NOT to exclude "Nerve Block Injections" from coverage but to exclude ONLY THERAPEUTIC Medial Branch Blocks. Nerve block injections is far too generic a term and could be misrepresented to include diagnostic nerve block procedures of many different types.

The decisions ONLY cover therapeutic injections and NOT diagnostic blocks. Diagnostic blocks were not considered in the key questions, SPECTRUM report, or discussed at the March 18th, 2011 HTCC meeting. Diagnostic blocks include, but are not limited to, diagnostic transforaminal injections (aka spinal nerve root block), diagnostic medial branch blocks, and diagnostic intraarticular joint (facet/sacroiliac) injections. The decision document should stress the coverage decisions only pertain to therapeutic and not diagnostic spinal injections.

Epidural steroid injections are NOT just for frank radiculopathy but for radicular pain. Radiculopathy requires a neurologic deficit to be present, radicular pain does not. Epidural steroid injections are a primary treatment to treat pain and are most appropriate even without a neurologic deficit.

I ask that you amend this document to reflect what was agreed to by the HTCC on March 18th, 2011

Sincerely,

Doug Burns, MD

--

Doug Burns, MD

www.spineinjections.org

May 10, 2011

C. Craig Blackmore, M.D., MPH
Chair
Washington State Health Technology Clinical Committee
P.O. Box 42712
Olympia, WA 98504-2712

RE: Draft Report of Findings and Coverage Decision for Coverage Topic # 20110318B – Spinal Injections – March 18, 2011 HTCC Meeting

Dear Dr. Blackmore,

The International Spine Intervention Society (ISIS), a multi-specialty association of 3,000 physicians committed to the development, evaluation, validation, education and advocacy of percutaneous techniques used in the diagnosis and treatment of spine disorders; would like to take this opportunity to provide comments regarding the **Draft** Report of Findings and Coverage Decision of the Health Technology Clinical Committee from March 18, 2011 review of spinal injections.

First, we would like to point out that the extreme complexity and overly broad nature of the topic made the Committee's task very difficult. We would also like to reiterate our concerns with the process, as it is our belief that the Committee's task was further complicated by the poor quality of the technology assessment and the inadequate availability and input of the contracted expert during the meeting. Despite this, the Committee did an admirable job of preparing itself by thoroughly sifting through the large volume of data and carefully deliberating. Indeed, the sincere efforts of the individual committee members were the highlight of the process.

In light of the hard work of the Committee, and based on the decisions that were made, we offer the following comments:

Content

1. HTCC Coverage Determination Section (Page 1)

We would like to draw the Committee's attention to a significant discrepancy between the information contained in the report and the decisions made by the Committee during the meeting. Namely, the report does not differentiate between diagnostic and therapeutic medial branch blocks. **The Committee decision pertained only to therapeutic medial**

**International
Spine Intervention Society**

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San Rafael, California 94903
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branch blocks. The Committee made it very clear that they were only making a decision on therapeutic medial branch blocks, as the evidence report and the key questions addressed therapeutic blocks only. Additionally, the specific procedure “medial branch blocks” have been inappropriately referred to as “nerve block injections”. To avoid confusion, the Report should be revised to assure the coverage determination accurately reflects the Committee decision.

The key questions, the Spectrum report and the discussion at the HTCC meeting only evaluated therapeutic spinal injections and not diagnostic spinal procedures. Diagnostic blocks include, but are not limited to, diagnostic medial branch blocks, transforaminal (spinal nerve root) injections and intraarticular joint injections. The final decision document should state that this decision only pertains to therapeutic spinal injections and not diagnostic spinal injections.

2. Major Complications (Section #2 of Committee Findings)
We would like to point out that vascular puncture should not be listed under major, but rather under minor complications.

We offer the following suggestions for revisions to the Draft Report:

Page 1, HTCC Coverage Determination Section

“Nerve Block Injections, Intradiscal Injections and Facet Injections are not a covered benefit”

should be replaced with:

“Therapeutic Medial Branch Blocks, Intradiscal Injections and Facet Injections are not a covered benefit”

“Lumbar Epidural Injections; Cervical-thoracic Epidural Injections and Sacroiliac Joint Injections are a covered benefit for the treatment of chronic spinal pain and associated radiculopathies”

should be replaced with:

“Lumbar Epidural Injections; Cervical-thoracic Epidural Injections and Sacroiliac Joint Injections are a covered benefit for the treatment of chronic spinal pain and primary radicular pain”

Page 1, Limitations of Coverage Section

“For treatment of chronic spinal pain and associated radiculopathies”

should be replaced with:

“For treatment of chronic spinal pain and radicular pain”

Page 4, #2 “Is the technology safe”

Statement under Major Complications:

“Vascular Puncture: the evidence based technology assessment report indicated the mean incidence of intravascular puncture following fluoroscopically guided lumbar spinal injections was 10.18% (range, 1.9–22%) as reported in five case series designed to assess its incidence. “

Should be moved to the next section on Minor Complications

We thank you for this opportunity to comment on this very important issue and offer our ongoing input and expertise in this process. If we can answer any questions or provide any assistance, please feel free to contact Margaret Klys, Director of Health Policy at the International Spine Intervention Society (ISIS) at mklys@spinalinjection.org or 708-505-9416.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Way Yin', with a stylized flourish extending to the right.

Way Yin, MD
President
International Spine Intervention Society

To whom it may concern,

I am a fellowship trained and board certified Pain Medicine subspecialist physician in Seattle.

I was personally in attendance for the entirety of the HTCC March 18, 2011 spinal injections meeting.

I have reviewed document 20110318B – Spinal Injections regarding Spinal Injections.

Document 20110318B – Spinal Injections states that "Nerve Block Injections" are not a covered benefit.

I would like to point out the glaringly clear lack of understanding your organization has about interventional pain management which was illustrated during the HTCC meeting. "Nerve Block Injections" were never reviewed by the HTCC, nor were they discussed on March 18, 2011. In fact, "Nerve Block Injections" is a broad term that refers to the injection of local anesthetic to any nerve, anywhere in the body.

To those of us who were in attendance on March 18, 2011, it was VERY clear that the decision was not to exclude "Nerve Block Injections" from coverage, but rather to exclude ONLY THERAPEUTIC (and NOT diagnostic) Medial Branch Blocks.

Therapeutic (and NOT diagnostic) medial branch blocks are very specific blocks of a very specific nerve for very specific reasons. The exclusion of THERAPEUTIC (and NOT diagnostic) medial branch blocks ***does not equate to the exclusion of ALL "Nerve Block Injections" by any means.*** There are literally HUNDREDS of nerve block injections performed in the practice of Pain Medicine!

You should understand the difference. That you do not once again illustrates your organization's incompetence in attempting to ration the practice of medicine and the subspecialty of Pain Medicine in particular.

Sincerely, Jason Attaman

--

Dr. Attaman, PLLC

Worthless State Employee Sounds Off

This week I went to my physician so that I could get a spinal injection to help me work and live more comfortably despite suffering from chronic and sometimes debilitating back pain. Simply put, these injections allow me to walk, work and function daily without the complicating effects of narcotic pain pills.

Once at the appointment I was told by physician staff that despite having private medical insurance for which I pay high premiums, deductible and co-pays, because I am a state employee, I am ineligible to get such services.

Yes, I am one of those infamous Washington State Employees, some politicians and citizens have recently chosen to vilify due to the current economic upheaval in the state of Washington. I knew when I chose this career path almost 19 years ago that my labors as a parole/community corrections officer would go largely unnoticed and at times unappreciated by many. Nevertheless, with good intentions, I was happy to dedicate my life's work to serve and protect the citizens, victims and the community of the state of Washington in exchange for little to no accolades. I felt my efforts were important to my community and the state of Washington. Many of you will never know the lives we save every day.

Over the last decade, state employees in Washington have been overlooked for nominal cost of living raises and we have watched helplessly as our healthcare cost keep rising. Parole officers along with other state employees sacrificed one day's pay a month, by complying with mandatory furlough days and also watched as hundreds of other staff were let go in an effort to do our part to balance the budget, a budget mismanaged by those government officials, we the people elected to protect and oversee such matters.

In July our paychecks will be reduced by 3% and we will experience yet another hike in our health care premiums.

Until now I have remained silent, anxiously watching for budget cuts and proposals as they trickled down to impact me, my co-workers and their dependants. Despite popular belief, Washington State Employees do not get paid handsomely and our pensions and health care coverage pale in comparison to that of the private sector. The truth is, most public servants on the front-line are people who are dedicated to helping others.

Like many other Washington State Citizens I choose to work, pay my bills on time and make fiscally sound decisions with a meager and rapidly shrinking paycheck. I am forced to balance my home and health care costs despite increasing economic, political and social adversities which are closing in around us.

Last month a publicized committee of government officials and physicians met to determine state employees, who pay for their own private health care costs, were not important enough to receive basic pain management care in the form of spinal injections. It seems because state employees work to provide services some may deem unsavory, state employees are less deserving than the rest of the working class covered by the very same insurance companies.

As a working citizen, public servant and member of the human race, I have recently been dealt a profound and sobering blow by our presiding government and those who are lucky enough to be in an entitled position to make such crippling decisions for those less fortunate. I have finally accepted and come to understand that in the eyes of the Washington State Government, my life's work, livelihood and personal health are simply irrelevant.

K. Master

Your executive summary of the Spinal Injections decision(s) looks good. I think Gary pointed out that the more general term “nerve blocks” might be better identified by the more specific term “medial branch blocks”, but other than that, I have no suggestions of a medical nature.

I think it is worth commenting that, when I last looked at reimbursement for fluoroscopic guidance and CT guidance, the reimbursement for fluoroscopic guidance for spinal injections was very substantially less than the reimbursement for CT guidance for the same injections. In the vast majority of cases, fluoroscopic guidance is a perfectly acceptable means of properly placing the needle for the injection. If reimbursement remains substantially more for CT guidance than for fluoroscopic guidance, the phrase “with fluoroscopic guidance or CT guidance” will almost certainly produce increased utilization of CT guidance compared to its present utilization, due solely to its increased reimbursement. My recommendation, therefore, is for the medical directors to consider suggesting to the committee that it reword the phrase above, perhaps as follows: “With fluoroscopic guidance, or, only in those cases in which it fluoroscopic guidance is contraindicated, CT guidance.” Alternatively, I suppose the present wording could be maintained if the text of the decision makes it very clear that CT guidance is to be used only when fluoroscopic guidance is contraindicated or is incapable of providing the necessary level of imaging detail.

My comments in the paragraph above also apply to SI joint injections.

Thank you.

Lee Glass



7075 Veterans Boulevard, Burr Ridge, IL 60527
Toll-free: (866) 960-6277 Phone: (630) 230-3600
Fax: (630) 230-3700 Web: www.spine.org

May 10, 2011

C. Craig Blackmore, MD, MPH
Chair
Washington State Health Technology Clinical Committee
P.O. Box 42712
Olympia, WA 98504-2712

Dear Dr. Blackmore:

I am writing on behalf of the North American Spine Society (NASS) to comment on the Washington State Health Care Authority Health Technological Clinical Committee Findings and Coverage Decisions on the topic of spinal injections. We welcome the opportunity to comment on the above determination related to therapeutic spinal injections and hope you perceive our input as constructive toward establishing a policy that meets the goal of practicing cost effective, evidence based medicine, while simultaneously balancing the needs of patients with chronic pain. We acknowledge the difficulty inherent in reviewing literature with conflicting outcomes, limited studies with the highest quality methodology, and subsequently applying this information to develop a policy that is both cost effective and humane.

The policy states that cervical, thoracic, and lumbar epidural steroid injections are considered a covered benefit for the treatment of chronic spinal pain and associated radiculopathies in patients who have failed conservative measures. For clarification, the intent of the committee was to allow for epidural steroid injections for radicular pain and not only for those with frank radiculopathies. Additionally, epidural steroid injections in this decision involve the performance of all methods of epidural administration including the interlaminar, transforaminal and caudal route and this should be reflected in the final decision. The documentation of efficacy and limiting the number of injections to 3 in a 6 month period is a reasonable cost containment policy. However, we would like to clarify that this refers to a body region, rather than the whole body. Patients may develop a cervical radiculopathy, have that successfully treated, and at some point within the year develop a lumbar radiculopathy. This obviously would need to be treated separately. Having this clarified in the document, may avoid unfair and unnecessary denials of care.

We are pleased that therapeutic sacroiliac joint injections are a covered benefit. We trust that a repeat sacroiliac injection(s) will be allowed if the patient obtains adequate pain relief and functional improvement for a reasonable time frame.

Based on the current literature, we feel the determination not to cover intradiscal steroid injections is appropriate given the lack of compelling clinical benefit in trials and the potential risk of infection with repeated injection.

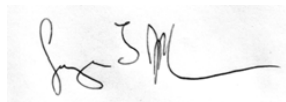
C. Craig Blackmore, MD, MPH
May 10, 2011
Page 2

There are areas of the policy we feel need further development and clarification. The policy states that nerve block injections are not a covered benefit. At the time of the HTCC hearing the only therapeutic nerve block procedure that was being evaluated was therapeutic medial branch blocks. We request you change this terminology to therapeutic medial branch blocks rather than nerve block injections. Nerve block nomenclature is usually reserved in discussion of diagnostic blocks such as diagnostic transforminal injections or diagnostic medial branch blocks. The key questions, the Spectrum report and the discussion at the HTCC meeting was only focused on therapeutic spinal injections and not diagnostic procedures. Diagnostic blocks, include, but are not limited to diagnostic medial branch blocks, transforminal (spinal nerve root) injections and intraarticular joint injections. The final decision document should state that this decision only pertains to therapeutic spinal injections and not diagnostic spinal injections.

Furthermore, we feel that the denial of facet injections is unwarranted. Chronic axial low back pain is a common condition affecting 5% of the population. Options for managing this condition are numerous, yet response among individuals to each of these treatments is variable. Available treatments include but are not limited to diet, exercise, physical therapy, manipulation, behavioral modification, medications, spinal injections, and spinal fusion. In patients who fail less invasive methods, facet injections blocks have a role in the management of this condition. Rather than categorically denying these services, we favor the use of clinical selection criteria, exclusion criteria, and documentation of efficacy before a repeat injection could be performed. Such criteria include axial back pain greater than limb pain, pain with lumbar extension, palpation tenderness over the facet joint, imaging evidence of zygapophyseal joint degenerative change, and persistence of pain and functional deficit despite conservative measures before a facet injection be considered. A subset of patients experience lasting benefit from facet injections. A reasonable method to allow for a repeat procedure that could be considered is that which Noridian, the Medicare carrier for Washington state utilizes, which includes a minimum of 50% pain relief and functional improvement for a minimum of 3 months before a repeat injection be allowed. If this degree of relief consistently occurs, then no more than 3-4 injections/year would be a reasonable limit.

We hope our comments will be used in a meaningful way to the development of cost effective, evidence based, clinically useful, and socially compassionate policy to help manage patients with chronic back and neck pain.

Sincerely,

A handwritten signature in black ink, appearing to read "Gregory Przybylski". The signature is written in a cursive style with a long horizontal stroke at the end.

Gregory Przybylski, MD, President
North American Spine Society

To whom it may concern,

I had a spinal injection in Nov. of 2010, it is now May 1st. I got so much relief from it I am thinking of trying another one. The pain has just started to return. Within two weeks after injection I had less pain and less tingling down my right leg. My all over feeling was a 95% improvement. The arthritis in middle back was even less pain. The bulging disk in neck and lower back were less painful. If not for this injection I would suffer a lot. I am 66 years and very frightened to have any surgery on my back. This injection is a life safer for less pain. Please do not stop coverage for this procedure; it is less expensive than a surgery and less invasive.

Thank you,
Patsy Podeseck
408 Birch Av.
Richland Wa. 99352

5.7.11

To Whom it May Concern,

I am writing to you to comment on the Draft HTCC Findings and Coverage Decision document regarding Spinal Injections that was released by the HTA and open for public comment until May 10, 2011.

I was present at the HTCC hearing and wish to add some clarification to what was released in the draft decision document.

Specifically:

The decision was NOT to exclude "Nerve Block Injections" from coverage but to exclude ONLY THERAPEUTIC Medial Branch Blocks. Nerve block injections is far too generic a term and could be misrepresented to include diagnostic nerve block procedures of many different types.

The decisions ONLY cover therapeutic injections and NOT diagnostic blocks. Diagnostic blocks were not considered in the key questions, SPECTRUM report, or discussed at the March 18th, 2011 HTCC meeting. Diagnostic blocks include, but are not limited to, diagnostic transforaminal injections (aka spinal nerve root block), diagnostic medial branch blocks, and diagnostic intraarticular joint (facet/sacroiliac) injections. The decision document should stress the coverage decisions only pertain to therapeutic and not diagnostic spinal injections.

Epidural steroid injections are NOT just for frank radiculopathy but for radicular pain. Radiculopathy requires a neurologic deficit to be present, radicular pain does not. Epidural steroid injections are a primary treatment to treat pain and are most appropriate even without a neurologic deficit.

I ask that you amend this document to reflect what was agreed to by the HTCC on March 18th, 2011

Sincerely,

Paul Dreyfuss, MD

Dear Committee,

This email is in regard to the proposed elimination of spinal injections for the relief of back pain for the injured worker. I am in complete disagreement with your experts opinion that this is not a viable alternative. I am also a grateful recipient of the procedure and feel it has extended my career.

I have been in the fire service for 28 years. As you may be aware, back injuries are one of the leading causes of a shortened fire fighter career. During my career I have also been a certified paramedic for 26 of those work years. While I have experienced strains during my tenure, in 2007 I experienced my worst back injuries while bringing a unruly patient out of a basement that resulted in a bulging disc at L4-L5. Rather than managing my pain with pharmaceutical techniques, my physician suggested I consider spinal injections. I awoke from the procedure completely pain free and when I stood up my wife stated, "I have not seen you stand this straight in years". I was back to work approximately 2 weeks later with only one follow-up.

I have many friends in the fire service that have had the same procedure with similar results. Additionally, I have seen the results of pain management with drugs in my community. Simply put, many have become addicts. I have many friends that will swear that oxycotin (the drug prescribed most) is a very hard monkey to get off your back. Not to mention, there are simply many professions that does not allow for pain management via pharmaceuticals, mine included.

I am requesting that you do workers and the communities right by continuing to allow this procedure as an alternative for pain management.

Sincerely,

Ricky J. Walsh
Captain, Richland FD
509-999-3090
62103 E 44 PRNE
Benton City, WA 99320