

## Health Technology Clinical Committee

### Findings and Coverage Decision

**Topic:** Implantable Drug Delivery Systems for Chronic Non-cancer Pain (IDDS)

**Meeting Date:** August 15, 2008

**Final Adoption:**

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#### Number and Coverage Topic

20080815A – Implantable Drug Delivery Systems (IDDS).

#### HTCC Coverage Determination

Implantable Drug Delivery Systems (IDDS) used for treatment of chronic, non-cancer pain are **not a covered benefit**. This decision does not apply to the use of IDDS for other purposes.

#### HTCC Reimbursement Determination

- ❖ **Limitations of Coverage**  
Not Applicable
- ❖ **Non-Covered Indicators**  
Chronic Non-cancer Pain
- ❖ **Agency Contact Information**

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

#### Health Technology Background

Chronic non-cancer pain (CNCP) is an important and common medical concern worldwide. The International Association for Study of Pain defines chronic pain as pain lasting beyond the normal time of healing, defined as three months or longer. The most common source is low back pain. Prevalence rates of chronic pain (any severity) are estimated to be as high as 55% and an estimated 9% of Americans have moderate to severe CNCP.

Most individuals find adequate relief from conservative therapy or treatment of underlying/co-morbid condition, including oral and injectable medication, cognitive-behavioral therapy, exercise, spinal manipulation, interdisciplinary rehabilitation. However, an estimated 1% to 20% has pain resistant to treatment or unacceptable side effects and more invasive therapies are considered.

IDDS is a device which is fully surgically implanted into the patient to provide round-the clock long-term drug therapy. In a surgical procedure, the pump itself is implanted, usually in the abdomen, and a catheter is tunneled to the site of drug delivery. IDDS pumps have typically been used for chemotherapy, spasticity,

Draft version not officially adopted yet

cancer pain, and chronic non-cancer pain. This review focuses solely on use for patients with chronic, non-cancer pain.

Potential Benefits that an IDDS may have are:

- Lower dose and effective pain relief by delivery of opioids direct to spinal cord (instead of systemic oral/injected)
- Fewer side effects due to lower dose/direct administration
- Better pain control leads to:
  - Improved quality of life
  - Improved functional status
  - Improved employment status
- Reduced addiction/tolerance
- Patient convenience

Potential drawbacks:

- IDDS treatment is invasive, prone to side-effects and complications, costly, and requires a large amount of technical support (Williams et al. INHATA Review, 2000)
- Safety Issues
  - Overdose of infused medications
  - Infused drug side effects
  - Device/ Mechanical pump complications
  - Surgical Complications
- Invasive procedure that is an additional method to deliver opioids (not replacement or different treatment mechanism for individuals with chronic pain)
- Tolerance and dose escalation of infused and adjunct oral medications
- Permanent implantation implications
  - Non-life threatening condition with unknown resolution
  - Generally middle age candidates
  - Maintenance and revisions required –risks with each surgery; long term patient and provider commitment
- Costs and specialty provider availability for long term

### **Summary of Committee Findings**

Brian Budenholzer, Committee Chair, led a discussion of the evidence related to the safety, efficacy, and cost effectiveness of Implantable Infusion Pumps beginning with identification of key factors and health outcomes, and then a discussion of what evidence existed on those factors.

### **Key Factors and Health Outcomes Considered**

**Efficacy:** The committee identified multiple key health outcomes that were important for consideration in their overall decision on whether the technology was effective. Summary of committee consideration, discussion, comments

- Pain control - a primary studied outcome, important benefit to patient, substantial evidence that there is a pain control benefit for some patients, though evidence is weak due to low quality, patient population has few choices; pain is a subjective sensation so difficult to measure reliably, challenged assumption of little placebo affect in pain relief, unclear usefulness of VAS tool to measure pain where other tools may be more reliable and accurate, 143 patients in small case series is a small evidence base, information doesn't identify how to select patients, benefits are spotty where some patients get stellar results and others get none, benefit durability.

- Functional Status - an important outcome to the committee, but only one study reported information and study low quality
- Employment Status – information from four case series low quality and results; local L&I data - no patient returned to work.
- Quality of life – while important outcome, studies did not report or very little data available
- Operator Use - discussion centered on several items related to the difference between the device itself and its “in practice” use. Primarily, discussion focused on who selects patients and performs the intervention, and whether restrictions, specialized training or other requirements were involved. Manufacturer does provide training; most are performed in hospital or facility and they have accreditation standards; only a small number of experienced practitioners used on L&I’s patients, and the 3 removals were a patient and provider joint decision. Best available information from case series – presume highly trained and highly selected patients still had 8% removal; 8% discontinuation; and 9% to 42% reoperation rate. Ultimately committee did not use as key factor.
- Dosage / addiction issues - issues related to dose escalation of injected medication; adjuvant therapy; reduction of other pain medicine and treatments; patients receiving oral medication have addiction and overdose risks. Ultimately committee did not use as key factor

**Safety:** The committee discussed multiple outcomes related to safety, but ultimately addressed safety as a whole, rather than by individual outcomes.

- A primary theme discussed is that the data on safety indicates that there are definite risks on safety, though unclear how often events occur, so can’t be sure that this is a safe procedure
- Agencies identified a 1 per 1000 death rate from a Medtronic document, but not validated
- 9 deaths in 2006 was concerning – whether operator error or device, the coverage is for both
- Case series represents somewhat of a best case scenario and adverse events reported included 8% discontinuation due to adverse events; 8% discontinuation due to no pain relief; 9 to 42% reoperation rate.
- Unclear whether discontinuation should be treated as an adverse or safety event, if not working, it is appropriate and positively viewed that it is removed (efficacy issue).
- Safety data represents a substantial risk to patients and procedure is performed where there is a serious, though not life threatening underlying condition
- No data presented on whether there are differences with other pump implantation uses (e.g. cancer)
- Maude Data voluntarily reported – since 1996 –total number of adverse events was over 9000 and ECRI filtered to about 900 based on their desire not to include other pump usage like insulin; categories of adverse events (deaths, serious injuries, malfunctions, other) not broken out
- Medical treatment has risks as well – personal experience with patients is addiction to drugs, overdose, depression common in these and so inconclusive about whether this infusion intervention will have more safety issue

**Cost:** The committee discussed cost and cost-effectiveness as a whole. This topic generated the least discussion because of the primary safety and effectiveness issues.

- General comments that costs appeared to be about equivalent or inconclusive cost-effectiveness (premature) because effectiveness not yet established
- There are a number of costs related to the pump including: screening; initial purchase; pump implantation; medication refills; consultations; complications; adjunctive medications; pump replacement or removal.
- 4 cost analysis were included and rated as inconclusive. Committee discussed briefly deLissovoy (1997) a five year cost model that showed: non-pump cost of \$83,000; and pump costs ranging from a best case of \$53,000, average of \$83,000, and worst case of \$125,000. For the Reden

and Anders analysis, questions were raised about the appropriateness of the cost basis used for non-pump costs – (\$4k/month) may not be representative.

### **HTCC Implantable Infusion Pump Coverage Decision**

The HTCC reviewed and considered a comprehensive 2008 HTA Evidence Report on IDDS for chronic, non cancer pain that identified 549 potential articles and included and analyzed the relevant and highest quality studies: 13 case series, 4 cost analysis, and 1 combined case series and cost analysis. The committee also reviewed information provided by the Administrator, state agencies, and public members; and heard comments from the evidence reviewer, HTA program, agency medical director, a device manufacturer panel, and several public members.

Committee members focused on the question about whether this device, which presents a different (and maybe better) way of administering drugs, but is an invasive way of treating a non-life threatening condition that often involves multiple invasive procedures. There was a focus on an overall or net health benefit question weighing generally agreed weak evidence of pain improvement versus the lack of evidence on other key health outcomes, and the data showing significant safety events.

Representative summary comments included:

- Substantial amount of evidence on pain control, though weak, available to guide committee; patient population do not have a lot of options but it would not too hard to design a trial that would give us better than weak evidence;
- appears that there is a modest pain benefit from procedure
- Safety data represents a substantial risk to patients and procedure is performed where there is not a life threatening underlying condition
- Concerned about safety evidence raised unanswered questions that were not present previously; weak evidence of efficacy of patient pain relief in a proportion of patients
- Possible benefit but should be tightly controlled to best identify those who could benefit
- Quality of evidence is not robust, but there is a lot. Case series issues: eight of sixteen studies funded by industry, and even with that, evidence is not overwhelming that is extremely effective and there are safety concerns raised by what is a best case scenario, combined with safety issues raised by local data
- Risk is greater than benefit
- Evidence doesn't tell how to select patients, benefits are spotty where some patients get stellar results and others get none
- Medical treatment has risks as well – personal experience with these patients is addiction to drugs, overdose, depression common in these and so inconclusive about whether this intervention will have more safety issue
- Pain is a subjective sensation and sole focus of looking at pain relief, there is some evidence that it is useful; issue remains about global pain control
- Have most up to date evidence that exists, and safety data,
- All evidence equals methodologically flawed case series which is not sufficient to base decisions about care on and that do not have - there isn't trial data necessary to be confident
- Data on safety indicates that there are definite risks on safety, though unclear how often risks occur so can't be sure that this is a safe procedure
- Cost effectiveness not a large factor – appears to be fairly equal
- Evidence is based on small case series of only a 143 patients related to pain relief, and is a small number; case series can be hypothesis raising; general rule that case series tends to overstate benefit and understate risks;
- Question about whether the device is a great device, but not used well (could be operator error); moved by patients that commented that had good results and mindful of patients no longer with us that couldn't make comments

- Need better information – this is a different way of administering drugs – case series may demonstrate that this may be a better way to administer drugs, but data does not show that

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

### **Committee Discussion related to Expert Treatment Guidelines and Medicare Decision**

Decision is consistent with two of three expert guidelines, and not consistent with Medicare's decision to cover conditionally.

- Medicare coverage decision was in 1994, no overwhelming efficacy evidence developed since then, and the Maude (safety) data was not available at all
- Approach of clinical decision making has changed substantially since 1994 and 2004 with focus need for strong clinical evidence is a new approach that these decisions did not account for
- Majority of the committee did not feel that evidence presented shows that the technology is equivalent or more effective
- Majority of committee did not feel evidence presented show the technology is safer;
- Majority of committee did not feel evidence presented showed that the technology is cost-effective
- Committee decision is based on all evidence, including the vendor, public, agency medical directors and report while it is unclear what information Medicare decision relied on.

### **Committee Authority**

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