Washington State Health Care Authority, HTA Program
Implantable Drug Delivery System
Final Key Questions and Background

Introduction

HTA has selected Implantable Drug Delivery Systems (IDDS) to undergo a health technology assessment where an independent vendor will systematically review the evidence available on the safety, efficacy, and cost-effectiveness. HTA has posted the topic to gather public input about what evidence is available and should be considered. HTA posted Draft Key Questions to gather input about the key questions, has reviewed the public comment and has finalized key questions. These final key questions will now guide the development of the evidence report. Once completed, a draft report will be published for review and public comment.

Final Key Questions

Implantable drug delivery systems are devices used to deliver drugs to a specific site in the body to treat pain, spasticity, and cancer over a long term.

When used to treat persons with chronic, non-cancer pain:

1. What's the evidence of efficacy and effectiveness of implantable infusion pumps?
2. What is the safety profile of implantable infusion pumps?
3. What are the cost implications and cost effectiveness for implantable infusion pumps?
4. Is there any evidence of differential efficacy or safety issues among special populations?

Safety

In considering the safety profile, the following events will be considered:

a. Mortality
b. Inflammatory masses
c. Infections
d. Severe peripheral edema / severe pruritis
e. New neurological complaints / findings (paralysis, weakness, sensory loss, reflex change, bladder problems)
f. Evidence of need for revision and replacement
g. Problems related to off-label use (e.g. non-approved drugs)
h. Opiod over-dosage (e.g., related to malfunctions)
i. Longer term adverse events such as suppression of gonadotrophic hormones, and respiratory depression or sleep apnea

Cost

When considering cost impacts, the following information will be included:

a. Cost per year of use (including equipment, replacement, and drug cost)
    i. Duration of use (failure and discontinuation rate)
    ii. Escalation of drug dose or additional types of drugs
b. Comparative costs of non pump treatment; and
c. Cost per quality adjusted life year

Technology Background

Disease: Chronic non-malignant pain, usually defined as pain of at least 6 months' duration, is a debilitating, complex condition involving neurophysiologic, cognitive, behavioral, cultural, social, and economic factors. Diagnosis generally involves a medical evaluation typically including a history and physical examination and diagnostic work-up if necessary and a psychological evaluation typically including mental status examination, psychological testing as needed, and determination of the suitability of the patient to undergo certain interventions.

Treatments: Due to the complexity of the causes of this condition, there are numerous treatment options for patients with chronic pain, and response is difficult to predict. Treatment strategies for chronic non-malignant pain generally begin with the least invasive and low risk interventions and progress if the treatments are not effective. Treatment usually involves a combination of interventions. The use of opioid and other analgesic medications for the treatment of chronic non-malignant pain is prevalent, although there is concern when used for treating non-malignant pain due to risks associated with long-term use (e.g., tolerance, pain, addiction). Some patients develop adverse effects from medications or do not experience adequate pain control from the medications. Pain medication delivery through an IDDS is an alternative to delivery of medication orally.

Technology: Implantable drug delivery systems deliver an active drug to a target organ or body compartment for prolonged periods of time. The pump is surgically implanted underneath the skin, operates by battery, and connects to a tube or catheter that is placed in the appropriate body area. For treatment of chronic non-cancer pain, the catheter is usually placed intra-spinally. Implantable infusion pumps have FDA approval for treatment of chronic non-cancer pain when used to administer opiods (morphine) and an analgesic (zicontide).

Implantable infusion pumps could potentially provide benefits of more effective pain control by administration directly to the target area; lower drug doses; and reduced side effects or toxicities of the drugs. However, potential harms include the surgical risks, device failures or complications, and drug overdose if inappropriately used or monitored. Primary concerns include safety concerns over the long term usage (patients generally have 20+ year life expectancy); FDA recalls and safety alerts; and invasive procedure risks and complications, and contraindications. Efficacy concerns include duration and degree pain control, and improvements in functional and quality of life outcomes. Finally, there are cost concerns related to the high initial costs for implantation and device, maintenance and costs of adverse events due related to the surgical placement of the device compared to alternatives, including no cost for delivery of oral medication.