AIS Healthcare

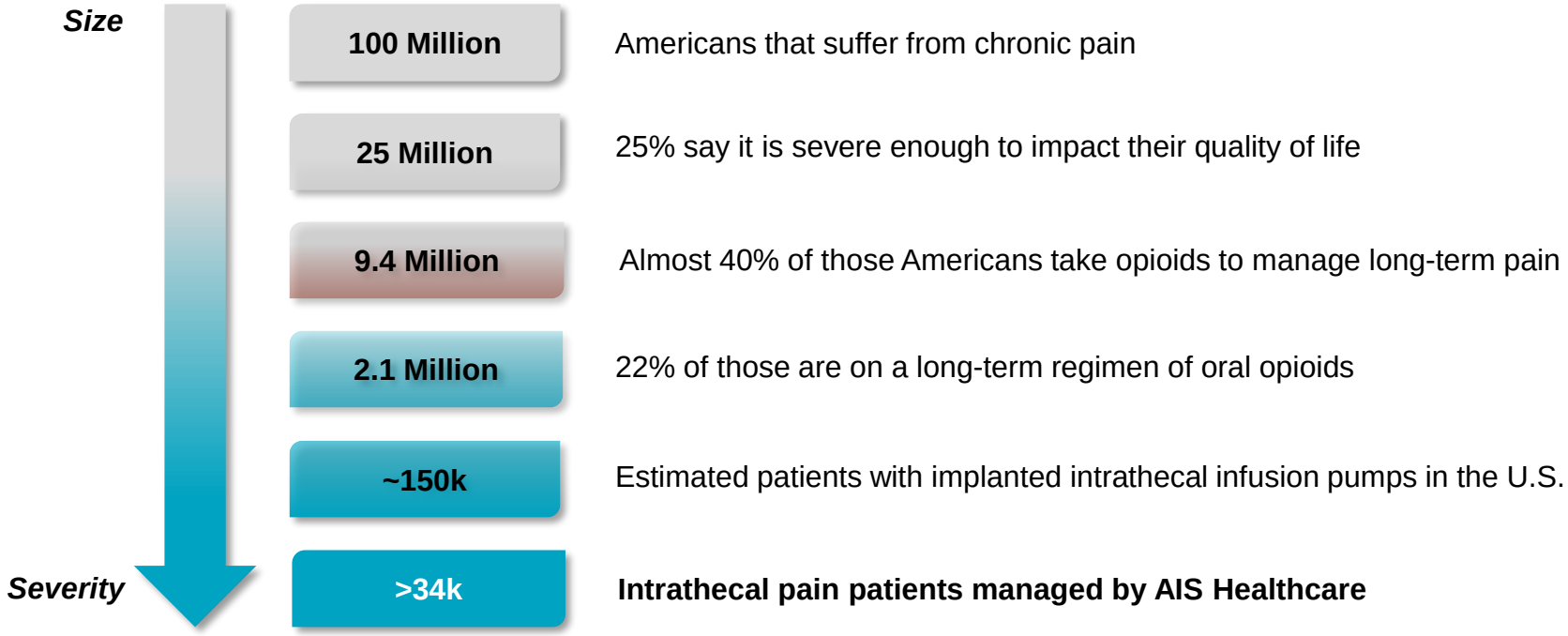
Advancing quality. Improving lives.

An overview of AIS Healthcare

May 9, 2022

Pain is an American epidemic

Chronic pain impacts a massive portion of the U.S. population



AIS Healthcare manages the most severe population of chronic pain patients:

- Individuals that have exhausted all other forms of therapy/surgery and are at risk for opioid abuse
- A population that experiences high rates of co-morbidities and can be prone to hospitalization
- A population that, if managed improperly, can become extremely costly to the health care system

Source: National Institutes of Health; Time Magazine “Why American Can’t Kick Its Painkiller Problem”

Background: Pain Pumps

- As an alternative to high doses of oral opioids, some patients with severe chronic pain are prescribed an implantable pain pump.
- The pump is surgically implanted in a patient's abdomen and slowly delivers pain medication into the fluid around the patient's spinal cord (the intrathecal space) via a catheter.
- Approximately 150,000 patients across the United States currently utilize pain pumps.
- The average patient is over 50, disabled, and has had multiple back surgeries. Intrathecal pumps are also used to manage uncontrolled pain in patients with cancer and other serious medical conditions.

Background: Pain Pumps, cont.

- The pump is refilled by a medical professional every 60-90 days (4 to 5 times per year) via a needle that is inserted into the patient's abdomen and then into the pump itself.
- This procedure is usually performed in a provider's office, but also in a patient's home.
- The medication delivered via the pump is typically a combination of multiple opioids and muscle relaxants. Physicians write a prescription tailored to the particular patient, which is then compounded by a specialized pharmacy.
- Intrathecal pain pumps substantially reduce patients' use of oral opioids, which in turn significantly reduces abuse and diversion.

John’s patient journey

The physical and emotional toll of chronic pain

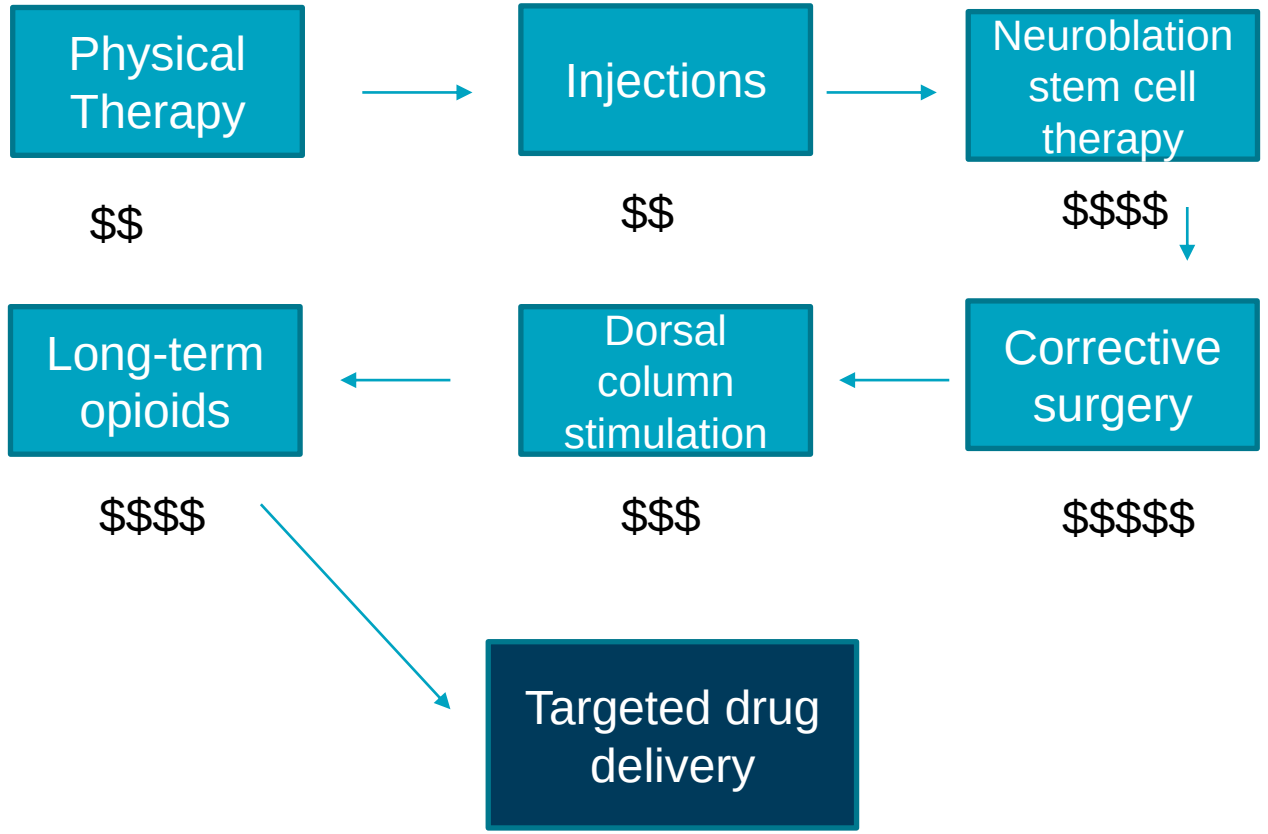
BACKGROUND

+ Work injuries resulted in chronic pain and multiple back surgeries
+ Continued pain led to decreased functional capabilities
+ Inability to walk without aid
+ Unable to drive to work
+ Side effects included headaches, dizziness, numbness, and pain in extremities
+ Oral medications included pain medication and muscle relaxants leading to “fogginess”
+ Experienced depression and weight gain
+ Inability to engage with family and friends

John’s patient journey

The associated costs of interventions before Targeted Drug Delivery

+ Many patients with chronic pain like John suffer through various treatments and interventions, each with associated costs, before receiving targeted drug delivery (TDD)
+ Treatment failures, such as failed back surgeries, also carry associated costs, like prolonged hospital stays or emergency room visits
+ **TDD shown to save, on average, ~$64k/Member/year.***



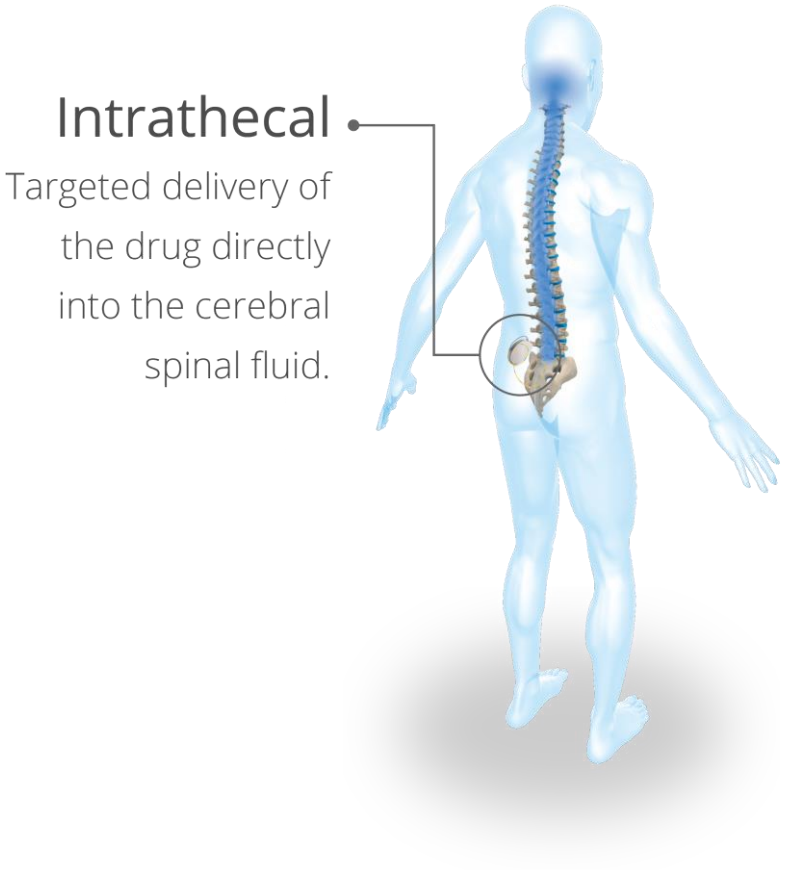
Assessment of Health Care Utilization and Cost of Targeted Drug Delivery and Conventional Medical Management vs Conventional Medical Management Alone for Patients with Cancer-Related Pain, Lisa J. Stearns, MD1; Sanjeet Narang, MD2,3; Robert E. Albright Jr, MD4; et al April 5, 2019.

Targeted Drug Delivery Care

Definition and Benefits

Targeted drug delivery, also known as intrathecal drug delivery, is the continuous administration of medication into the spinal canal via a catheter attached to a surgically implanted pump

+ Reduces need for oral medications
+ Directly delivers medication to a targeted area
+ Lowers medication doses when compared with oral medications
+ Reduces side effects associated with oral medications (*e.g.,* brain fog, sleepiness, upset stomach, constipation)
+ Medication compounded specifically for individual patient
+ Utilized in both pain and spasticity management
+ Delivered via physician's office or administered by a nurse at the patient's home



High quality TDD therapy and services leads to cost avoidance for payors

- Dealing with a **high-risk population of patients** prone to costly hospitalizations, urgent care visits, and expensive surgeries that fail
- Alternative therapies like long-term opioid use can lead to a host of other problems that are costly to treat (e.g., liver, kidney, and GI issues)
- Data has shown that the average patient on TDD therapy saves the healthcare system approximately ~$64,000/member/yr.
- Longer beyond-use dates avoid pharmacy waste (only with AIS compounded drugs)
- Hospitalization rates decrease due to: (only with AIS compounded drugs)
  - Elimination of medication errors
  - Stability and sterility of medication at the highest standards
  - No pump failures recorded from our medications
  - No need for recurring visits to physicians and/or refill frequency

Without AIS Healthcare and TDD, what are the options for other patients like John?

- Use of a low cost, lower quality from less safe pharmacy
- Prescribers modifying therapy to combinations of drugs that may maximize profits but may not produce desired results
- Pursuing other costly and less effective treatments like injections and physical therapy
- Switching to opioids which cause:
  - Depression, hallucination, drowsiness
  - Arrythmia, infection of cardiac lining and valves
  - Nausea/vomiting, reduced liver function
  - Seizure, muscle weakness
  - Difficulty breathing
  - Addiction, dependence, mood swings
  - More Hospital re-admissions
  - Higher inpatient and outpatient costs

2013 Medicare Reimbursement Change for Intrathecal Pain Therapy

- In 2011 and 2012 CMS issued two change requests (CR 7109 and 7397) articulating a policy change related to pharmacy billing for Medicare Part B drugs (including drugs used in intrathecal pain management).
- This decision was finalized in the CY2013 Medicare Physician Fee Schedule (PFS) rule, in which CMS envisioned that compounding pharmacies would shift their business models to contract with physicians to sell them intrathecal drugs, and the physicians would then bill Medicare for both the medication and their professional services.
- The policy represented a reversal of 20 years of payment precedent when it prohibited specialty pharmacies from billing Medicare directly for the drugs.

2013 Medicare Reimbursement Change for Intrathecal Pain Therapy, cont.

- As a result of CMS' 2013 PFS rule, many Medicare beneficiaries must either pay out-of-pocket for drugs that are covered by Medicare, or select treatments other than the one recommended by their doctor — typically, long-term use of high doses of oral opioids.
- This provision in the 2013 rule was based on administrative simplification, not policy, and it has had a very real impact on access to an important therapy among traditional Medicare beneficiaries.
    - Notably, all other payers, including Medicare Advantage, allow pharmacies to bill directly for these drugs and avoid the "buy and bill" model.

2013 Medicare Reimbursement Change for Intrathecal Pain Therapy, cont.

- The population of patients using this therapy are frail and may miss appointments, placing the physician at financial risk for drugs that may not be able to be administered and will need to be wasted.
- As a result, physicians may instead turn to other forms of pain treatment for their patients, including oral opioids, even if intrathecal pain therapy is the best clinical option. Adjust the therapy to use only drugs for which they are reimbursed for or make money from, and are incented to use a low-cost pharmacy, placing patients' health and wellbeing at risk
- Unfortunately, the COVID-19 crisis has substantially worsened this problem and is exposing many more Medicare beneficiaries to a horrible choice: pay out-of-pocket for their medication, or fail to have their pump refilled and face potentially life-threatening consequences. Since the pump cannot go dry, the pump will have to be explanted.

Thank you