OPPS Payment for Innovative Non-Opioid Post-Surgical Pain Medications to Prevent Opioid Related Adverse Events & Addiction

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Summary of Presentation

CMS Form 20017 Checklist

Presenters*

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CPT and HCPCS Codes Involved

- Application in process

APCs Affected

- All Surgical APCs

Description of the Issue

- Packaging pain management drugs administered at the end of surgery encourages the use of cheaper opioid analgesics and discourages the use of innovative non-opioid pain medications that reduce opioid exposure, addiction, and opioid-related adverse events.
- New non-opioid analgesics under development can be administered at the end of surgery to reduce the need for opioid analgesics for 72 hours after he patient leaves the recovery room.

Clinical Description of the Service

- HTX-011 is **in Phase 3 development for application** into the surgical site to reduce postoperative pain and the need for opioid analgesics for 72 hours. It was granted Fast Track Designation from the FDA in the fourth quarter of 2017 and Breakthrough Therapy Designation from the FDA in the second quarter of 2018.

Recommendations and Rationale for Change

- To unpackage innovative non-opioid post-surgical pain management drugs into either status indicator K or A since they are easily substituted outside the OPPS and they are an inconsistently administered preventive service.

Potential Consequences of Not Making the Change

- With over 50 million surgeries in the U.S. annually and over 80% of patients discharged with an opioid prescription, this translates to as many as 2.6 million new persistent opioid users, of which as many as 600,000 may develop opioid use disorder. This is important to Medicare for two reasons: (1) opioid-related adverse events cost billions of dollars annually and (2) opioid use disorder has nearly doubled among older Americans over the past 10 years.

* Disclosures: Dr. Viscusi and Mr. James Scott are paid consultants to Heron Therapeutics. Any opinions expressed by Dr. Viscusi are explicitly his own and not of Jefferson University, the American Society of Regional Anesthesia and Pain Medicine (ASRA), or any other entity.

The Need to Be Bold

On April 20, 2018, Secretary Azar renewed the determination that a nationwide public health emergency exists as a result of the opioid crisis.[1]

In a recent opinion piece, the Secretary added:

"America's opioid crisis…is a public health challenge of unprecedented scale. The worst drug crisis in the history of our country demands a serious response from leaders who are not afraid to be bold." [2]

1. HHS. https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-20Apr2018.aspx
2. HHS. https://www.hhs.gov/about/leadership/secretary/op-eds/our-commitment-fighting-opioid-crisis.html

Impact of the Opioid Crisis on the American Public and the Medicare Program

The opioid crisis is having a devastating impact on the U.S.

- Deaths from opioids contributed to a decrease in overall life expectancy between 2014 and 2015 – reversing consistent increases from 1970 to 2014. The CDC states “preventing opioid-related poisoning deaths will be important to achieving more robust increases in life expectancy once again” [3]

The economic cost is staggering

- New data on societal costs ($504.0 billion and over 50,000 American lives annually) highlight the need for additional urgency.[1]
- The entire Medicare and Medicaid programs cost $672.1 billion and $565.5 billion, respectively [2]

It is especially important to Medicare for two reasons:

- Opioid-related adverse events cost billions of dollars annually and
- Opioid use disorder has nearly doubled among older Americans over the past 10 years. [4]

1. Council of Economic Advisors. *The Underestimated Cost of the Opioid Crisis (November 2017).* https://www.whitehouse.gov/briefings-statements/cea-report-underestimated-cost-opioid-crisis/
2. CMS. *National Health Expenditure Fact Sheet.* https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html
3. Dowell D, Arias E, et al. *Contribution of Opioid-Involved Poisoning to the Change in Life Expectancy in the U.S. from 2010-2015 (Sept. 2017).* http://jamanetwork.com/journals/jama/article-abstract/2654372
4. SAMSA. *Opioid Misuse Increases Among Older Adults (July 25, 2017).* https://www.samhsa.gov/data/sites/default/files/report_3186/Spotlight-3186.html

The Surgical Setting is a Gateway to Addiction that Can Be Prevented

The surgical setting exposes more than 40 million patients annually to excess risk and potential addiction from opioids postoperatively [1,2]

- As many as 6.5% of these patients (~2.6M patients) that take opioids to manage pain after surgery may become persistent opioid users.[2] Of these patients up to 670,000 will develop Opioid Use Disorder (OUD) or addiction.[3]

Post-operative prescriptions put over a billion left-over opioids into medicine cabinets every year

- In 2012, more than 255 million opioid prescriptions were written in the U.S.[4]
- The surgical process accounted for 36.5% of total opioid prescriptions [3]
- A recent review of 6 studies showed 67-92% of patients reported unused opioids after surgery [5]
- 55% of people who misuse opioids obtain them from family or friends who have excess pills [6]

1. Center for Disease Control and Prevention, National Vital Statistics System. https://www.cdc.gov/nchs/nvss/vsrr/mortality.htm - Quarterly Provisional Estimates for Selected Indicators of Mortality, 2015–Quarter 2, 2017. Updated November 3, 2017. Accessed November 6, 2017. 2. Brummett CM et al. *JAMA Surg*. 2017;e170504. 3. CDC 2017: Centers for Disease Control and Prevention. Opioid Overdose: U.S. Prescribing Rates Map. Available at https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html. Accessed 8 March 2018. 6. Levy et al. *Am J Prev Med*. 2015;49(3):409-413. 5. Bicket et al. *JAMA Surg* 2017;152(11):1066-1071. 6. United States for Non-Dependence. Available at http://www.planagainstpain.com/resources/usnd/. Published September 2017. Accessed 28 February 2018.

Current Prospective Payment Systems Incentivize the Use of Inexpensive Opioids

- Under current policies, CMS considers “all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy.” [1]
- These policies result in providers receiving the same fixed fee whether the surgeon administers a non-opioid medication or not.
- Any costs the hospital incurs for creating and administering a multimodal pain management strategy get deducted from its fixed fee payment increasing hospital expenses without a corresponding increase in reimbursement.
- “Opioids are simple to prescribe, inexpensive, and pervasive”

1. 79 FR 66875

The Opportunity to Encourage the Use of Innovative Non-Opioid Treatments for Pain

President's Commission for Combating Drug Addiction and the Opioid Crisis: Final Report

Chris Christie's cover letter to the President outlining the Commission's final report:

The Commission heard from many innovative life sciences firms with new and promising products to treat patients' pain in non-addictive, safer ways; but they have trouble competing with cheap, generic opioids that are so widely used. **We should incentivize insurers and the government to pay for non-opioid treatments for pain beginning right in the operating room and at every treatment step along the way.**

Recommendation # 19:

The Commission recommends CMS review and modify rate-setting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate post-surgical pain.

Unpackaging Innovative Non-Opioid Treatments for Post-Surgical Pain

RECOMMENDATION:

To unpackage innovative non-opioid post-surgical pain management drugs into either status indicator K or A since they are easily substituted outside the OPPS and they are an inconsistently administered preventive service.

- The recommendation to unpackage innovative non-opioid post-surgical pain management drugs addresses a nationwide public health emergency, is consistent with longstanding prospective payment principles, and has precedence.

Policy Support for Unpackaging Innovative Non-Opioid Treatments for Post-Surgical Pain

- **Importance** – a nationwide public health emergency exists
- **Evidence** – guidelines, clinical process models, & checklists exist
- **Variation**
  - In contrast to international peers, up to 99% of patients who undergo major surgery in the U.S. are treated with an opioid analgesic. [1] For example, in a study of hip fracture patients in the US and Holland, 85% of the American patients and 58% of the Dutch patients were prescribed opioids in the hospital ($p<0.001$), and after discharge, 77% of the American patients and 0% of the Dutch patients were prescribed opioids ($p<0.001$). [2]
  - Despite guidelines and recommendations there is still significant variation in the use of non-opioids for post surgical pain. In a study in U.S hospitals, a large nationwide sample of surgical admissions observed significant variation in the utilization of non-opioid analgesics (95% of hospitals with a predicted probability of 42.6% to 99.2%) not accounted for by patient or hospital characteristics. [3]
- **Substitution**
  - Providers can easily substitute oral opioids paid under Part D for post-surgical pain management, defeating the purpose of including post-surgical analgesia in the surgical package.

1. Kessler ER, Shah M, Gruschkus SK, Raju A. *Cost and quality implications of opioid-based postsurgical pain control using administrative claims data from a large health system: opioid-related adverse events and their impact on clinical and economic outcomes*. Pharmacotherapy. 2013 Apr;33(4):383-91.
2. Lindenhovious AL, Helmerhorst GT, et al. *Differences in prescription of narcotic pain medication after operative treatment of hip and ankle fractures in the United States and The Netherlands*. J Trauma. 2009 Jul;67(1):160-4.
3. Ladha KS, Patorno E, et al. *Variations in the Use of Perioperative Multimodal Analgesic Therapy*. Anesthesiology. 2016 Apr; 124(4):837-845.

Policy Support for Unpackaging Innovative Non-Opioid Treatments for Post-Surgical Pain

- **Precedence**
  - In its Opioid Epidemic Roadmap, CMS recognizes effective, non-opioid treatment as a preventive service.[1]
  - 42 CFR §419.22(s) through (u) exclude certain preventive services from the OPPS. Exclusion of innovative non-opioid post-surgical pain management would also perform a preventive function by reducing opioid exposure for millions of Americans.
  - A case can also be made by looking at 42 CFR §419.22(k), which excludes durable medical equipment (DME) supplied by the hospital for the patient to take home except for DME that is implantable. Though post-surgical analgesia is inserted at the end of surgery, its primary benefit lasts well beyond the 8-hour period following surgery. It is also "consumed" in a patient's home much like DME.

1. CMS. https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Opioid-epidemic-roadmap.pdf

New Non-Opioid Pain Medications May Reduce Unnecessary Exposure to Opioids

- For example, in **completed but unpublished** Phase 3 trials of HTX-011, a **new investigational** non-opioid analgesic, 51% of patients undergoing hernia repair did not need any opioids throughout the critical 72-hour post-operative period. Of these, 80 (95.2%) and 71 (84.5%) remained opioid-free through day 10 and 28, respectively.
- These results were statistically significant versus the standard of care bupivacaine.
- The elimination of severe postoperative pain as seen with HTX-011 resulted in a significant decrease in the proportion of patients requiring any opioids following surgery, with over 90% of patients remaining opioid-free after discharge at Day 10 in both studies. **The implications of such findings are significant, given recent (2012) data showing that 86% of patients undergoing inguinal hernia repair filled an opioid prescription within 7 days of their procedure.** [1]

1. Wunsch H, Wijeysundera DN, Passarella MA, Neuman MD. Opioids prescribed after low-risk surgical procedures in the United States, 2004-2012. New Engl J Med 2016;315(15):1654-1657.

Conclusion

- By revising payment policies, CMS can encourage the use of innovative non-opioid pain medications and discourage the overreliance on opioids in the outpatient setting.
- We believe that unpackaging innovative non-opioid post-surgical pain management drugs into either status indicator K or A since they are easily substituted outside the OPPS and they are an inconsistently administered preventive service will help address Recommendation 19 and reduce the number of Americans unnecessarily exposed to opioids.

Thank You