

# OPPS Packaging Policy for Non-Opioid Pain Management Therapies

June 17, 2019

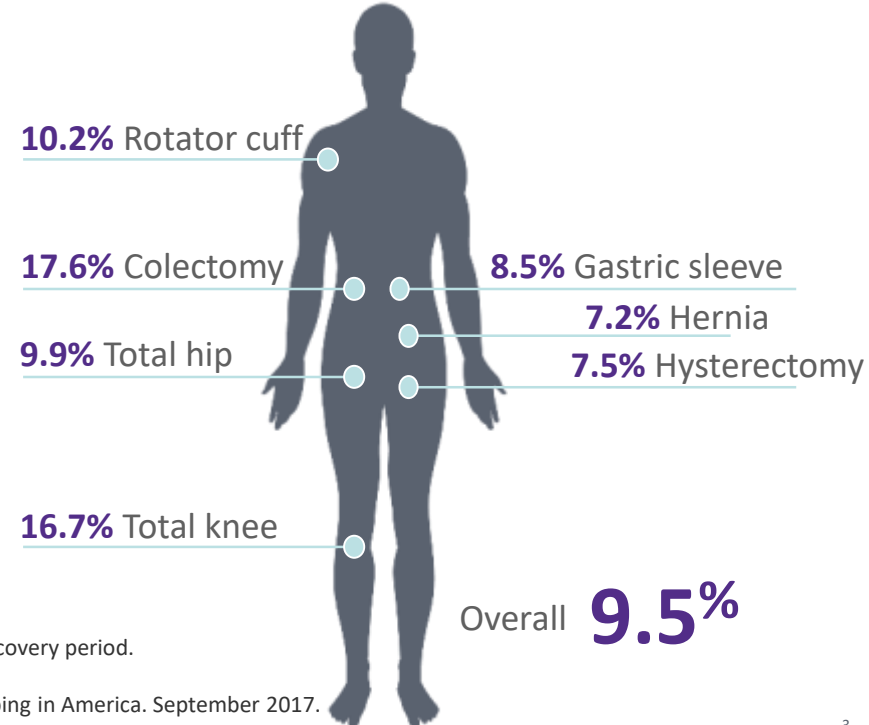
# Executive summary

- Medicare's surgical packaging policy continues to limit hospitals' use of non-opioid postsurgical pain management drugs like EXPAREL
- Medicare claims data show that only a small percentage of patients have access to EXPAREL to manage postsurgical pain – especially compared to the higher percentage of patients prescribed opioids for the same purpose
- The 2018 usage rate for EXPAREL in the top ten most common EXPAREL surgical procedures in the HOPD was 8.2%. This means only 8 of 100 surgical procedures involving Medicare beneficiaries in the HOPD used this effective non-opioid therapy to manage post-surgical pain.
- By excluding effective non-opioid therapies like EXPAREL from the surgical packaging policy in the CY2020 OPPS Rule, the Administration has an opportunity to reduce unnecessary opioid use with a budget-neutral policy change

# Managing postsurgical pain with opioids leads to persistent use, and contributes to the epidemic

- In 2013, **99%** of surgical patients received opioids to manage postsurgical pain<sup>1</sup>
  - Average prescription of **85 pills**<sup>2</sup>
- Nearly **3 million** individuals who had surgery in 2016 became persistent opioid users<sup>2</sup>
  - **2 million** of these patients were women<sup>2</sup>
- Overprescribing of opioids after surgery resulted in **3.3 billion** unused pills in 2016<sup>2</sup>

## Percent of newly persistent\* opioid patients by surgery<sup>2</sup>



\* Newly persistent defined as patients using an opioid 3-6 months beyond the postsurgical recovery period.

1. Kessler ER, Shah M, Gruschus SK, Raju A. Pharmacotherapy. 2013;33(4):383-391.

2. Pacira. United States for Non-Dependence: An Analysis of the Impact of Opioid Overprescribing in America. September 2017.

[Analysis in the report was based on research conducted by the Quintiles IMS Institute].

# Effective non-opioid options for Medicare beneficiaries exist

## EXPAREL: Non-opioid therapy for postsurgical pain relief

Long-acting formulation of bupivacaine, administered by infiltration, to produce postsurgical local analgesia; also used as a brachial plexus nerve block to produce regional analgesia for several days following surgery.



- Published data demonstrate EXPAREL reduces or eliminates postsurgical opioid consumption; a recent study of total knee replacements showed that compared to bupivacaine HCl, EXPAREL:
  - **Decreased opioid consumption by 78% through 48 and 72 hours** and provided significantly better pain control ( $P=0.0108$ , and  $P=0.0381$ , respectively)<sup>1</sup>
    - **10% of patients were opioid-free 48-72 hours** after surgery ( $P<0.01$ )<sup>1</sup>
    - **Patients  $\geq 65$  experienced a 90% reduction in opioids with better pain control;** ( $P=0.0016$  and  $P=0.0039$ , respectively); **14% of patients were opioid-free** ( $P=0.0218$ )<sup>2</sup>

1. Mont MA, Beaver WB, Dysart SH, Barrington JW, Del Gaizo DJ. The Journal of Arthroplasty. 2017.

2. Data on file. Pacira Pharmaceuticals, Inc.

# Medicare packaging policy state of play

- Since 2015, physician-administered pain management drugs like EXPAREL have been considered “packaged surgical supplies” for Medicare reimbursement in the hospital outpatient and ASC settings, and not eligible for separate reimbursement
- After concluding the policy limited patient access to non-opioid treatments in the ASC, CMS excluded EXPAREL from the surgical packaging policy in the ASC for 2019
- CMS declined to change payment in the hospital outpatient department, stating it had not found evidence that the surgical packaging policy discouraged the use of non-opioid, postsurgical pain treatments in the HOPD setting
- CMS stated it would continue to analyze evidence and monitor utilization of non-opioid options for potential future rulemaking

# National hospital survey on EXPAREL use: Methodology

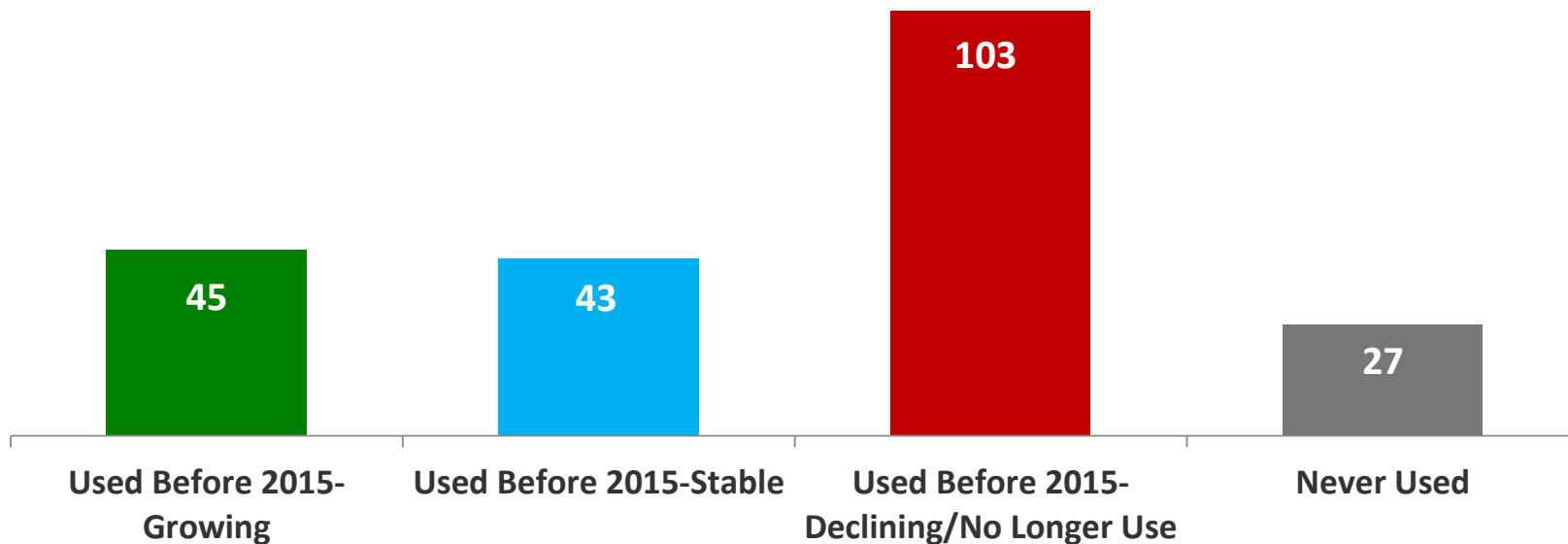
- Many hospitals and physicians have commented to CMS that the surgical packaging policy limited their access to EXPAREL and other non-opioid therapies in the hospital setting. The President's Opioid Commission reached the same conclusion
- In early 2019, the Berkeley Research Group (BRG) analyzed Medicare claims data for hospitals and performed an in-depth survey of 218 hospitals to understand considerations for non-opioid postsurgical treatments like EXPAREL
- BRG verified responses with Medicare claims data, hospitals were only included if they performed >1,000 outpatient surgeries each year

# Reimbursement policy is limiting treatment options

- BRG concluded that Medicare's surgical packaging policy has been the primary reason that a significant number of hospitals have reduced or stopped EXPAREL use since 2015:
  - **47% of hospitals reported EXPAREL use declined or stopped** since the surgical packaging policy went into effect in 2015
  - **89% of these hospitals identified financial concerns as the primary reason** for reduced EXPAREL use since 2015, highlighting the impact of Medicare's reimbursement policy on non-opioid utilization
- One-third of hospitals that have never used EXPAREL said "Medicare's policy" makes it a "non-starter" to request EXPAREL be added to the hospital's formulary
- 50% of hospitals that have stopped or reduced EXPAREL use reported that a change in the Medicare packaging policy would enable increased adoption of non-opioid treatments like EXPAREL

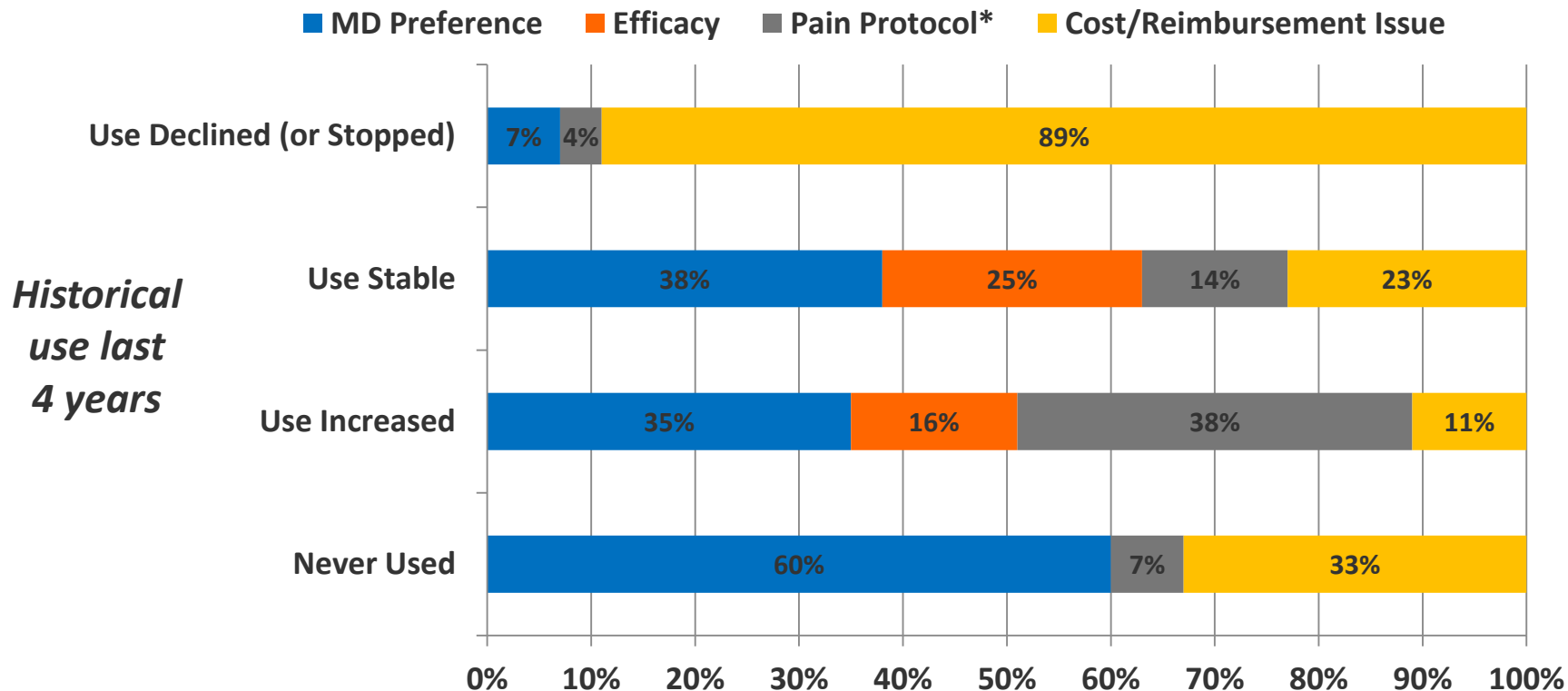
# Utilization trends for EXPAREL by hospital

## Utilization of EXPAREL by Hospital Respondents (N=218)





# Main drivers behind decision to use or not use EXPAREL

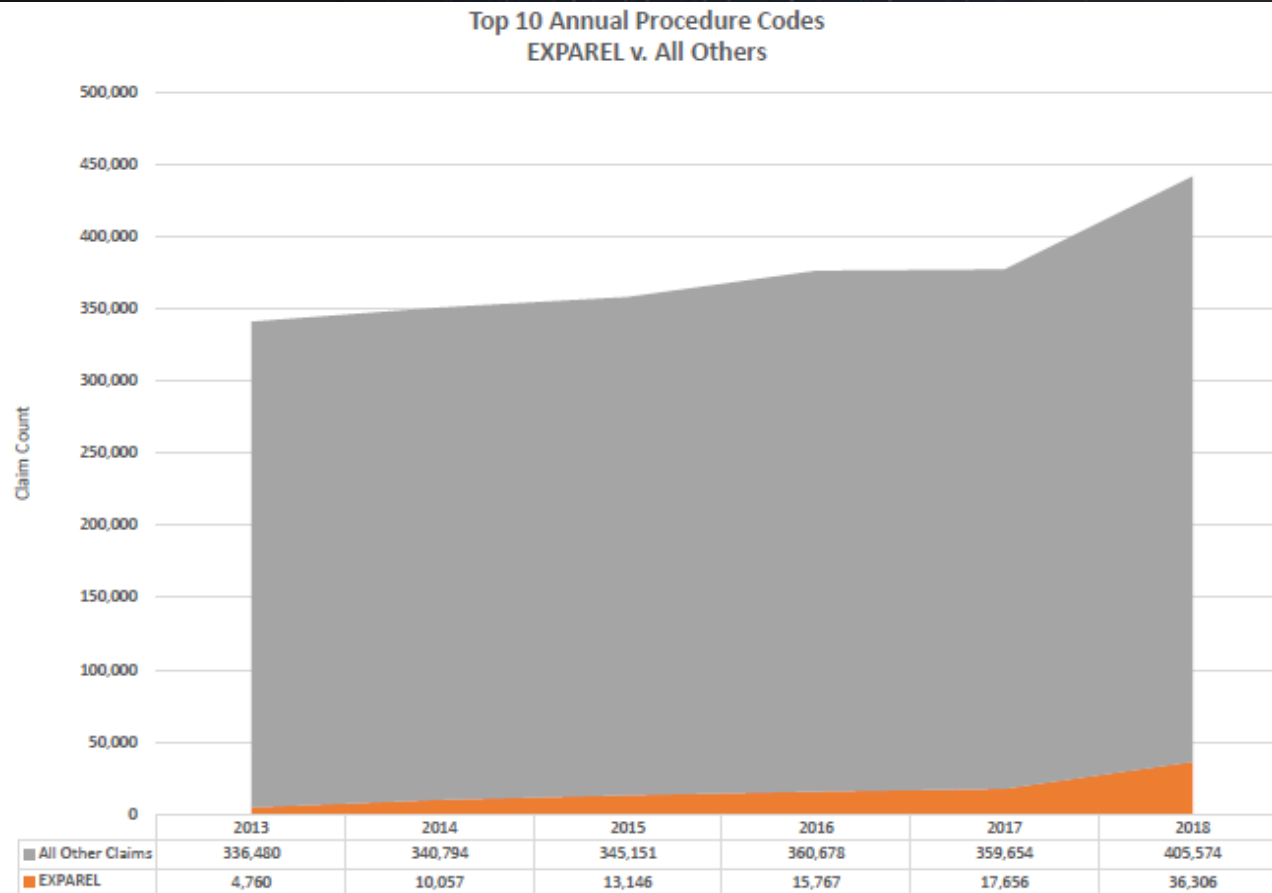


\*Pain protocol designed to reduce post-op opioid scripts

# Understanding EXPAREL use in 2018: Topline numbers do not tell the whole story

- Pain Management Best Practices Inter-Agency Task Force Final Report: **Called on CMS and other payers to “develop appropriate reimbursement policies”** to allow for greater use of multimodal, non-opioid therapies
- Part of CMS’ rationale to keep non-opioid therapies in the surgical packaging policy in the CY2019 OPPS was “topline” growth in EXPAREL units used in the HOPD since 2013
- The overall usage rate for EXPAREL in 2018, even in the top ten procedures by EXPAREL volume, was **8.2%**
  - Certain surgeries in the top 10 most common EXPAREL procedures show a low usage rate, such as **gallbladder removal (2.7%)** and **partial mastectomy (3.11%)**
- Until CMS changes the surgical packaging policy, providers and beneficiaries will not have necessary access to multimodal, non-opioid options to manage postsurgical pain

# EXPAREL usage in top 10 HOPD surgical procedures

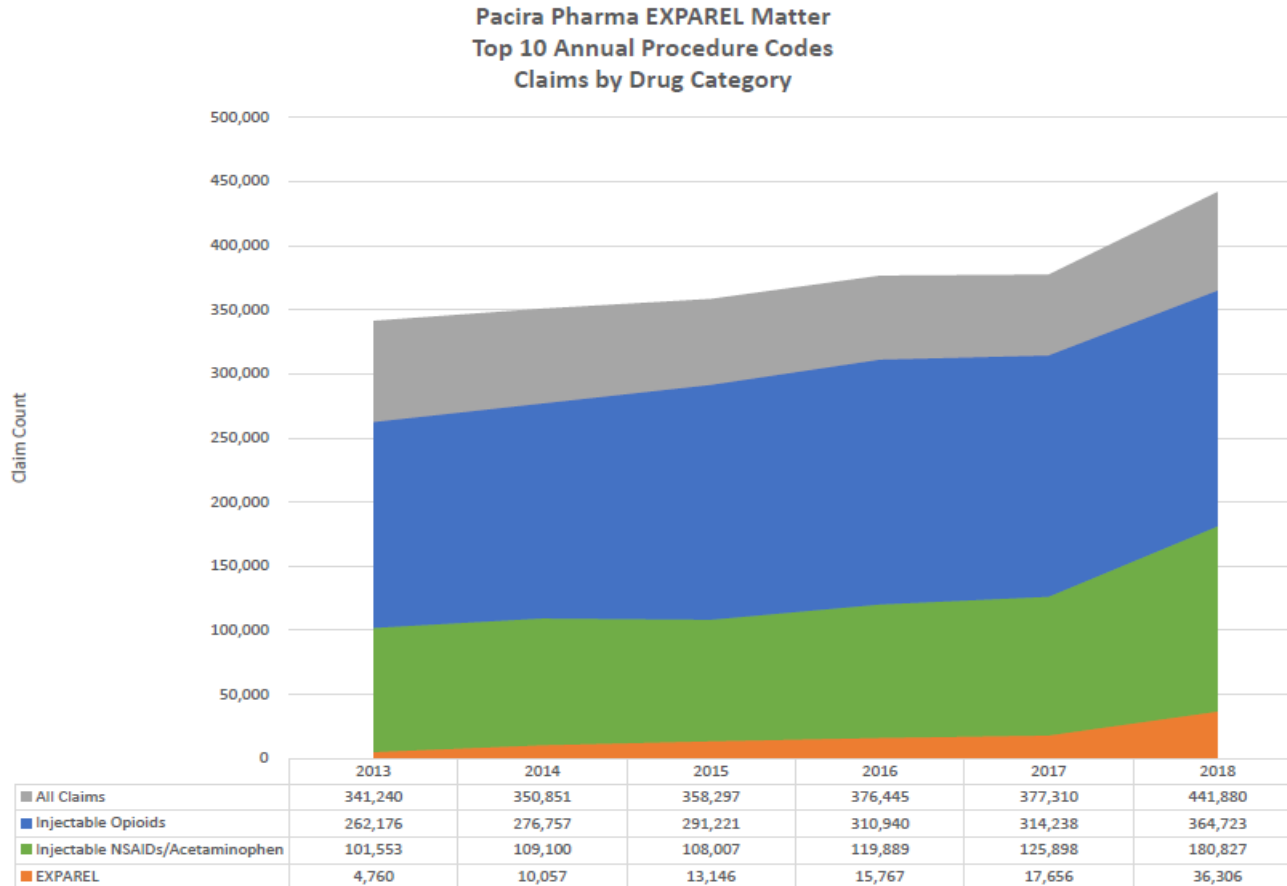


# EXPAREL vs opioids in the HOPD surgical procedures:

## Opioids still dominate

- While total EXPAREL use in the outpatient setting has increased over time, the EXPAREL usage rate continues to be low overall, **particularly compared to the opioid usage rate in the same procedures**
  - In 2018, in the top 10 most common procedures in which EXPAREL is used in the HOPD, EXPAREL's usage (percentage of procedures where EXPAREL was used) was **8.2%**
  - For the same set of procedures, the usage rate for injectable opioids that could potentially be replaced by EXPAREL is **ten times higher**, at **82.5%**
  - Since 2013, injectable opioids have been used in over 1.8 million of these procedures, about **18 times** the number of procedures that used EXPAREL (under 100,000)

# Comparing EXPAREL and opioid usage in top 10 HOPD surgical procedures



# Takeaways and conclusion

- The surgical packaging policy has continued to limit hospitals' use of non-opioid postsurgical pain management products like EXPAREL
- A meaningful number of hospitals have reduced or stopped using EXPAREL due to the lack of separate reimbursement. While CMS has focused on total EXPAREL utilization, this is an incomplete analysis that ignores financial barriers many hospitals face in transitioning away from opioids for postsurgical pain treatment
- The EXPAREL usage rate, even in its most common surgical procedures in the HOPD, remains artificially low, particularly when compared to opioid use
- These rigorous analyses support a modification of the OPPS surgical packaging policy to exclude EXPAREL in the CY 2020 OPPS rule
- Taking this step will incentivize a transition away from opioids, to non-opioid treatments, causing a corresponding decrease in opioid use in a budget-neutral manner