

OPPS Packaging Policy for Non-Opioid Pain Management Therapies

Presentation to the Advisory Panel on Hospital Outpatient Payment

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Form CMS-20017 Requirements

- Speakers

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- Eric Greig, Attorney, Latham & Watkins LLP (paid advisor)

- This issue involves EXPAREL, described by C9290 – Inj. Bupivacaine liposome. This drug is administered by infiltration to produce postsurgical local analgesia or as a brachial plexus nerve block to produce regional analgesia for several days following surgery. This issue is not specific to particular APCs.
- Issue: Medicare currently packages payment for non-opioid pain management therapies with the payment for the underlying surgical procedure. By not separately reimbursing for non-opioid pain management therapies, this policy incentivizes the use of comparatively inexpensive opioids.
- Recommendation and Rationale: In line with recommendations from the White House Opioid Commission and the recent HHS Inter-Agency Pain Management Best Practices Task Force, we request that this Panel recommend to CMS that non-opioid pain management therapies for postsurgical pain be removed from the packaging policy in the HOPD. This change will reduce unnecessary opioid use and encourage a transition away from opioids. If CMS does not make this change, providers' use of non-opioid alternatives will continue to be limited, resulting in continued unnecessary opioid use.

Executive summary

- Medicare's surgical packaging policy continues to limit hospitals' use of non-opioid postsurgical pain management drugs like EXPAREL, a non-opioid alternative proven to reduce or eliminate opioid use.
- A survey of a representative sample of hospitals, supported by analyses of Medicare claims data, showed the following:
 - A meaningful group of hospitals have limited and will continue to limit their EXPAREL use *driven by reimbursement concerns*; and
 - Only a small total 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
- We respectfully request that this Panel recommend to CMS that it exclude non-opioid pain management therapies from the surgical packaging policy.

EXPAREL, a proven non-opioid alternative for postsurgical pain management

- Pacira BioSciences, Inc. is a New Jersey-based specialty pharmaceutical company dedicated to innovation for acute and chronic pain, particularly in the postsurgical setting.
- EXPAREL is a long-acting formulation of bupivacaine administered by infiltration to produce postsurgical local analgesia or 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:
 - **In 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)¹
 - **When incorporated into an enhanced recovery pathway for Medicare patients undergoing total joint replacements: 84% of EXPAREL patients did not require any additional opioid prescriptions** beyond the initial 7-day prescription provided at discharge
 - Nationally, ~1 in 12 knee replacement patients (8.2%) remain on opioids 6 months after surgery



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

2. Van Horne A, Van Horne J. Enhanced Recovery After Surgery Pathway for Total Knee and Hip Arthroplasty Patients in a Medicare Population. American Association of Orthopaedic Surgeons Annual Meeting. Presented March 2019.

3. Goesling J, Moser SE, Zaidi B, et al. Trends and predictors of opioid use following total knee and total hip arthroplasty. *Pain*. 2016; 157(6):1259-1265.

Overview of current Medicare packaging policy

- 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.
- In the 2019 rulemaking, CMS declined to change payment in the hospital outpatient department, stating it had not found sufficient evidence that the surgical packaging policy discouraged the use of non-opioid, postsurgical pain treatments in the HOPD setting.
- In the 2020 OPPS proposed rule, CMS once again declined to change payment in the HOPD, citing topline growth in EXPAREL utilization.

National hospital survey on EXPAREL use

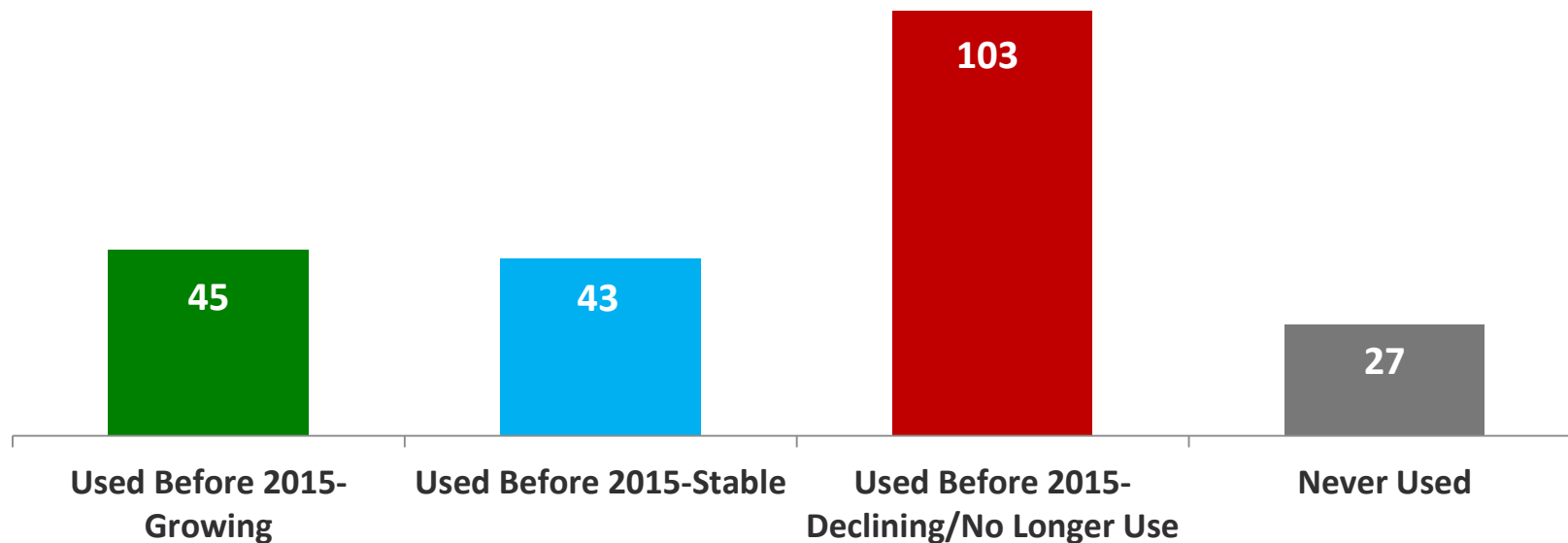
- Many hospitals and physicians have commented to CMS that the surgical packaging policy limited their access to EXPAREL and other non-opioid therapies in the hospital setting. The President's Opioid Commission reached the same conclusion.
- In early 2019, the Berkeley Research Group (BRG) analyzed Medicare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

Reimbursement policy is limiting treatment options

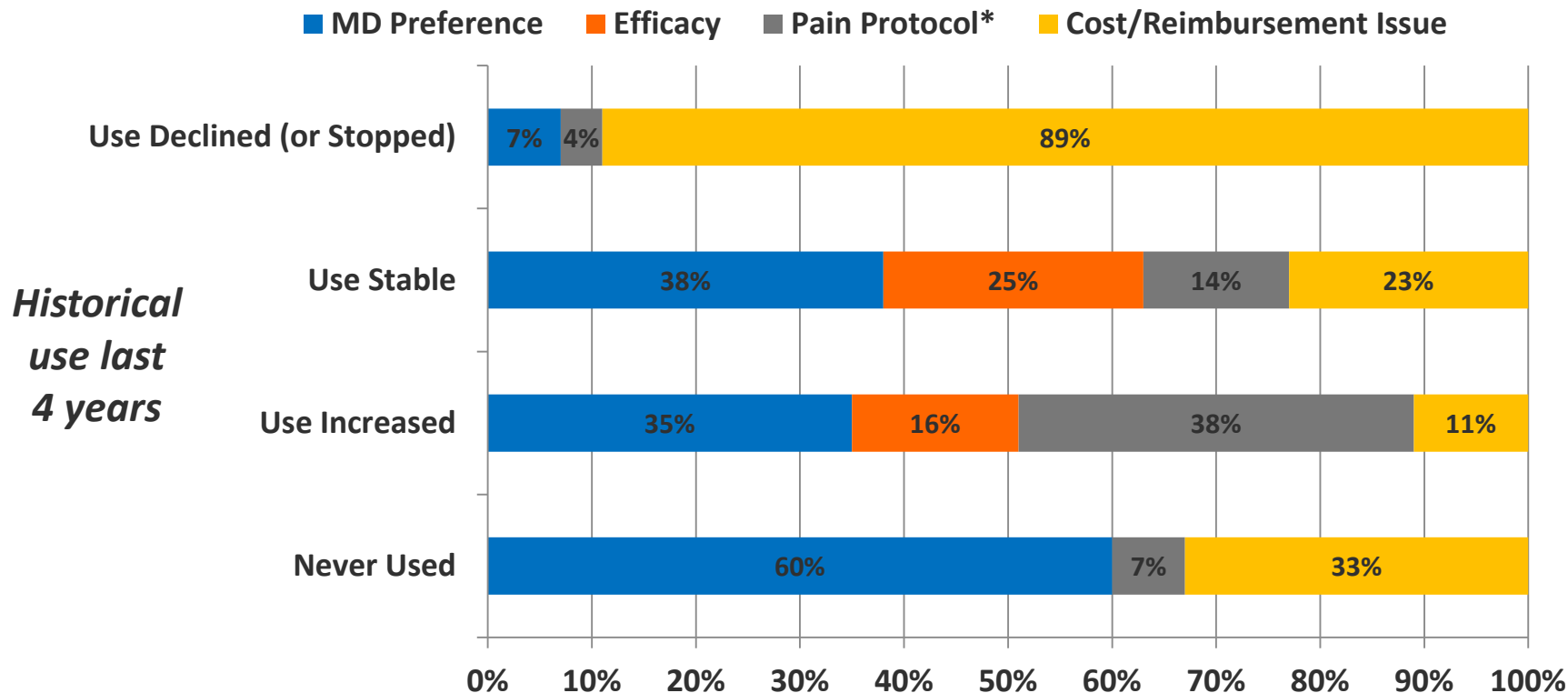
- BRG concluded that Medicare's surgical packaging policy has been the primary reason that a significant number of hospitals have reduced or stopped EXPAREL use since 2015:
 - 47% of hospitals reported EXPAREL use declined or stopped since the surgical packaging policy went into effect in 2015.
 - 89% 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

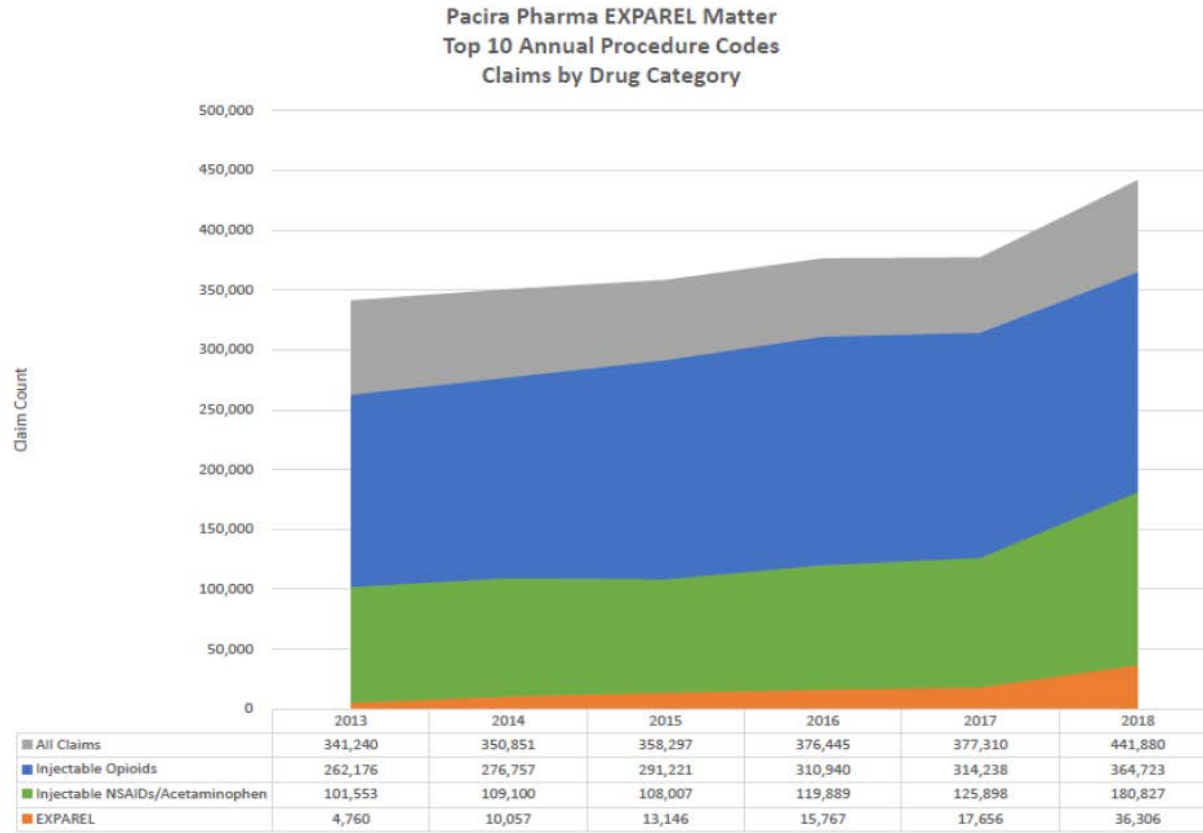
Utilization of EXPAREL by Hospital Respondents (N=218)



Hospitals with declining use since 2014 identify cost/reimbursement as the #1 reason for this trend



EXPAREL usage, even in its in top 10 HOPD procedures, is still significantly limited, especially compared to opioids



EXPAREL vs opioids in the HOPD

- Part of CMS' rationale to not exclude EXPAREL from the surgical packaging policy in the HOPD was growth in the “topline number” of EXPAREL units used in that setting from 2013 to 2018.
- 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).

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 post-surgical pain treatment.
- EXPAREL's usage rate, even in its most common surgical procedures in the HOPD, remains artificially low, particularly when compared to opioid use.
- We ask this Panel to recommend to CMS that non-opioid pain management therapies be removed from the surgical packaging policy in the CY 2020 OPPS final rule to spur a transition away from opioids.