

# Real-world Clinical and Health Economic Outcomes With Liposomal Bupivacaine in Medicare-Insured Patients Undergoing Outpatient Bunionectomy

Kewei Wang,<sup>1</sup> Priyanka Priyanka,<sup>1</sup> Jennifer H. Lin<sup>1</sup>

<sup>1</sup>Pacira BioSciences, Inc., Brisbane, CA

## STATEMENT OF INTENT

- 1 Patients often experience moderate-to-severe pain after orthopedic foot and ankle surgery that can last for several days if not weeks<sup>1</sup>; management of this pain is critical, particularly because these procedures are increasingly performed in outpatient settings<sup>2</sup>
- 2 Use of peripheral nerve blocks for lower extremity procedures can reduce opioid consumption and reduce postsurgical adverse events<sup>3,4</sup>
- 3 The NOPAIN Act expanded reimbursement for qualifying nonopioid therapies (eg, liposomal bupivacaine [LB]) for Medicare-insured patients undergoing outpatient procedures<sup>5</sup>
- 4 Real-world data regarding LB use for outpatient foot and ankle procedures in Medicare-insured patients are limited
- 5 This study evaluated the effects of LB on opioid use and healthcare utilization up to 6 months after discharge in Medicare-insured patients undergoing outpatient bunionectomy



PRESENTING AUTHOR: Jennifer H. Lin, Jennifer.Lin@pacira.com

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## METHODOLOGY

### STUDY DESIGN

- In this retrospective, cohort-based real-world study (2018-2022), effects of LB on opioid use and healthcare utilization were evaluated in adult Medicare-insured patients undergoing primary bunionectomy (CPT codes: 28110, 28292, 28296, 28297, 28298, 28299) in a hospital outpatient department setting between 2019 and 2021
- Data from these patients were extracted from
  - 20% Research Identifiable File Medicare Fee-for-Service claims data (Parts A, B, and D) and beneficiary enrollment/summary files under Centers for Medicare & Medicaid Services-Medicare Data Use Agreement 70419
- Patient records were excluded if they lacked continuous enrollment, had a diagnosis of end-stage renal disease, had inpatient surgery, or lacked data on surgical costs
- LB and non-LB cohorts with 6-month continuous enrollment before and after surgery were generated with 1:1 propensity score (PS) matching with 14 baseline covariates

## RESULTS

### PATIENT CHARACTERISTICS AND DEMOGRAPHICS AT SCREENING

- Of 1210 patients who underwent primary bunionectomy in outpatient hospital settings, 605 were in the LB cohort and 605 were in the non-LB cohort following PS matching (Table 1)
- Patient characteristics were balanced between cohorts (standardized mean difference <10%) following PS matching (Table 1)
  - Mean age ~71 years; ~80% female; ~90% white; ~55% with osteoarthritis; 18% with chronic pain
  - At baseline, more patients with prior opioid exposure reported chronic pain than those who had no prior opioid exposure (30% vs 18%)

**Table 1. Baseline Characteristics in Patients Undergoing Primary Bunionectomy in Hospital Outpatient Department Settings Between 2019 and 2021**

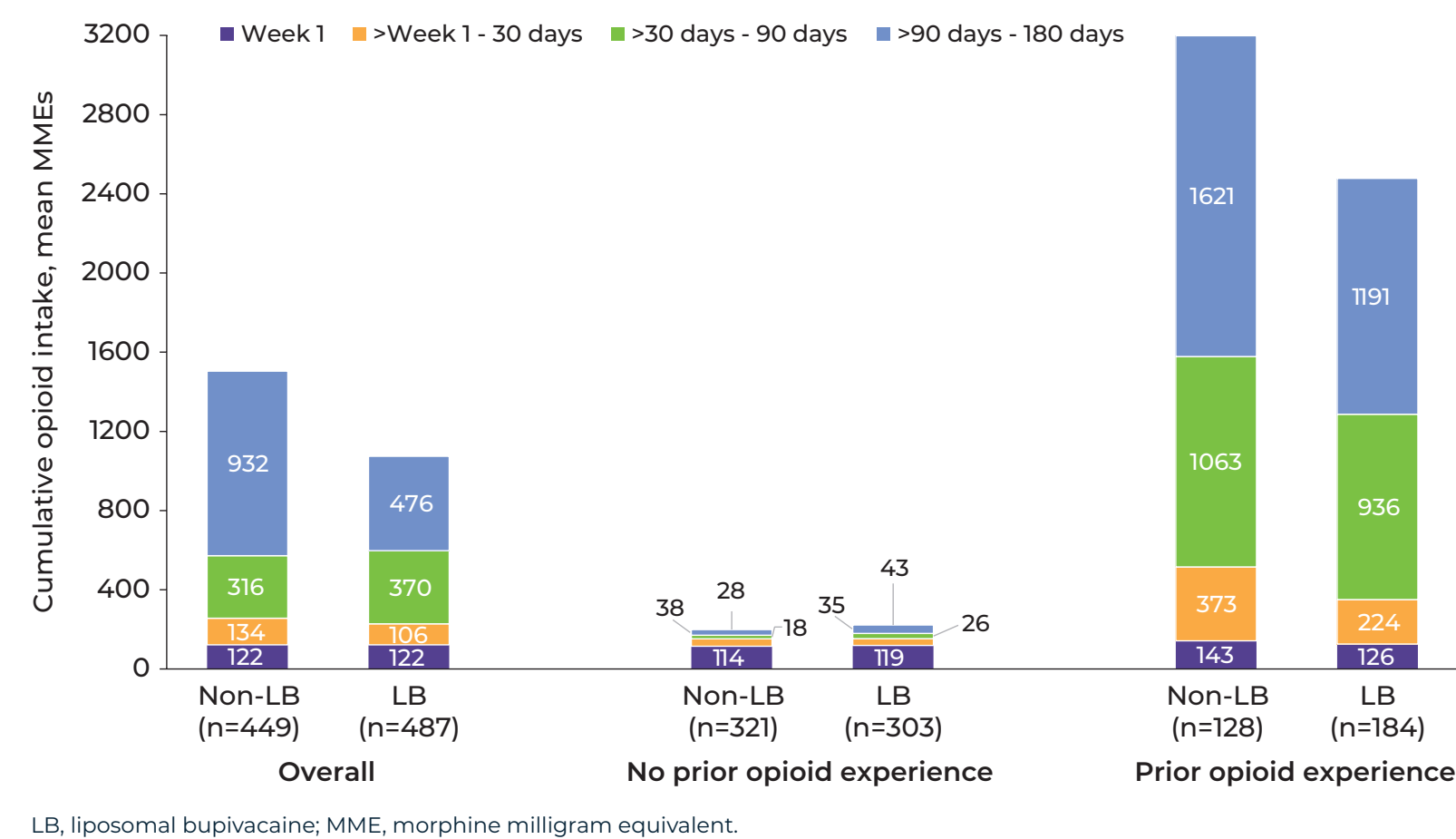
	After PS matching		SMD
	LB cohort (n=605)	Non-LB cohort (n=605)	
<b>Age, mean (SD), y</b>	71.4 (8.50)	71.7 (8.31)	0.035
<b>Male, n (%)</b>	122 (20.17)	120 (19.83)	0.008
<b>White, n (%)</b>	537 (88.76)	546 (90.25)	-0.049
<b>Region,* n (%)</b>			
Northeast	123 (20.3)	129 (21.3)	-0.024
Midwest	127 (30.0)	117 (19.3)	0.041
South	240 (39.7)	265 (43.8)	-0.084
West	114 (18.8)	93 (15.4)	0.092
<b>CCI, mean (SD)</b>	0.78 (1.37)	0.73 (1.38)	-0.044
<b>Anxiety, n (%)</b>	116 (19.17)	118 (19.50)	-0.008
<b>Chronic pain, n (%)</b>	122 (20.17)	99 (16.36)	0.099
<b>Depression, n (%)</b>	118 (19.50)	112 (18.51)	0.025
<b>Smoking, n (%)</b>	68 (11.24)	54 (8.93)	0.077
<b>Substance use disorder, n (%)</b>	19 (3.14)	18 (2.98)	0.096
<b>Osteoarthritis, n (%)</b>	345 (57.02)	329 (54.38)	0.053
<b>Obesity, n (%)</b>	124 (20.50)	99 (16.36%)	0.107
<b>Prior opioid exposure, n (%)</b>	184 (30.41)	128 (21.16)	0.213
<b>Surgical year, n (%)</b>			
2019	218 (36.03)	214 (35.37)	0.014
2020	182 (30.08)	187 (30.91)	-0.018
2021	205 (33.88)	204 (33.72)	0.003

\*1 patient in each cohort from "other" region.  
CCI, Charlson Comorbidity Index; PS, propensity score; SD, standard deviation.

### PRIOR OPIOID EXPOSURE AND CUMULATIVE OPIOID INTAKE

- Among ~80% of patients with Part D coverage (n=936), 312 had prior opioid exposure (Figure 1)
- During the first month after surgery, opioid intake was significantly lower in the overall LB versus non-LB cohort (227.9 vs 256.0 MMEs;  $P=0.049$ ) (Figure 1)
- Differences were more pronounced among patients with prior opioid exposure; the LB cohort had significantly lower opioid intake during the first postsurgical week (126.3 vs 142.5 MMEs;  $P=0.028$ ) and over 30 days (350.4 vs 515.5 MMEs;  $P<0.01$ ) versus the non-LB cohort (Figure 1)

**Figure 1. Cumulative opioid intake (in MMEs) at the 1-week, 30-day, 90-day, and 180-day follow-up.**

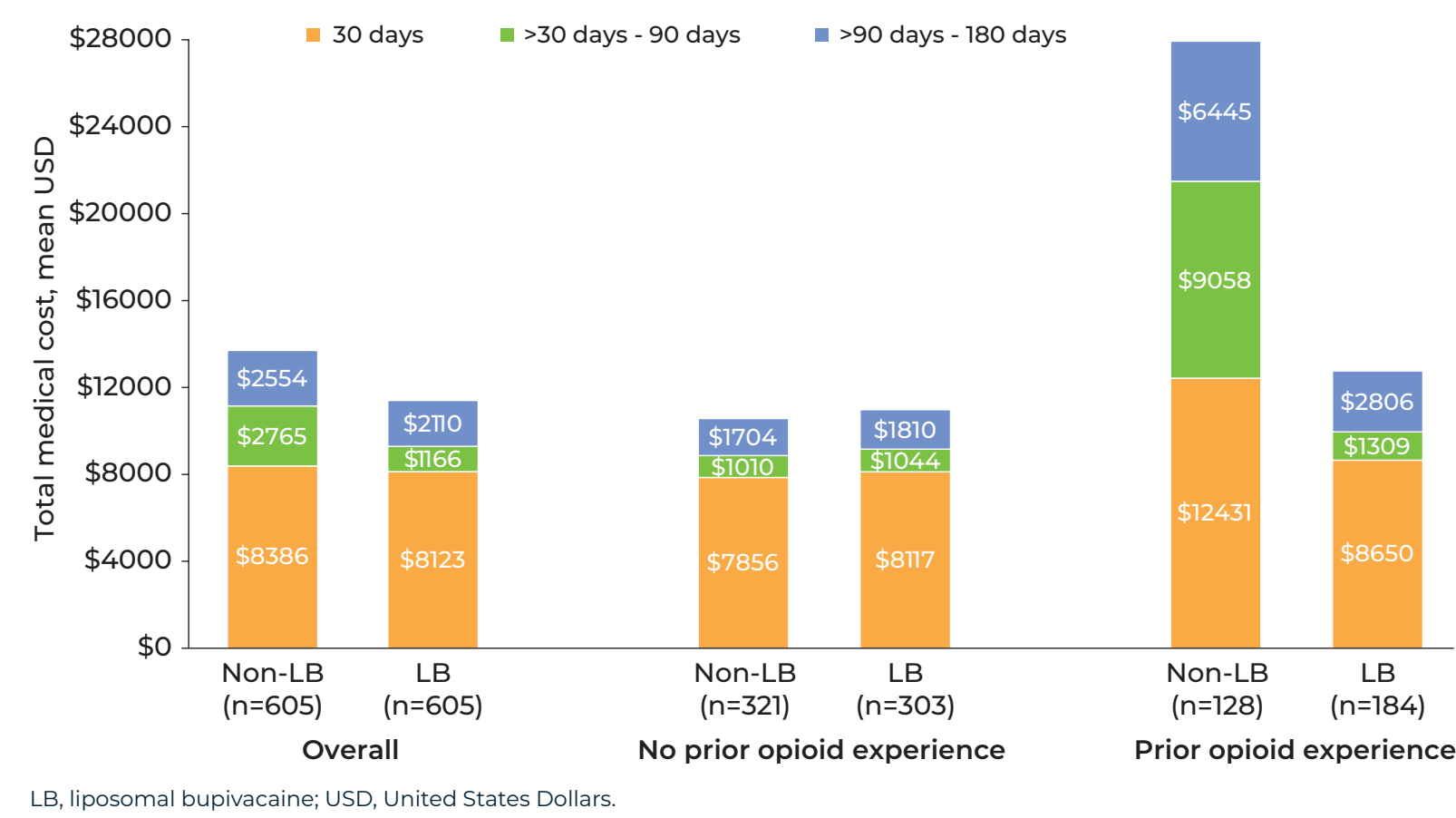


LB, liposomal bupivacaine; MME, morphine milligram equivalent.

### MEDICAL COSTS

- Index surgery cost for the LB and non-LB cohorts was \$7630 and \$6817, respectively
- Significantly lower medical costs were observed for the LB versus non-LB cohort at the 90-day follow-up (\$1862 savings with LB;  $P<0.001$ ), with more pronounced savings among patients with prior opioid exposure (LB vs non-LB: \$9959 vs \$21,489;  $P<0.001$ ) (Figure 2)
- Similar results occurred at the 180-day follow-up (\$2306 savings with LB;  $P<0.001$ ), with savings driven by opioid-exposed patients (\$15,169 savings with LB;  $P<0.0001$ ) (Figure 2)
- The drivers for cost savings during follow-up were attributable to inpatient and outpatient costs, followed by emergency department costs (Figure 3)
  - The cost savings in these healthcare categories were more pronounced in patients with prior opioid exposure; cost savings attributable to inpatient, outpatient, and ED categories were significant over 30 days ( $P<0.03$  for all)

**Figure 2. Total medical episode-of-care cost at the 30-day, 90-day, and 180-day follow-up for the LB and non-LB cohorts.**

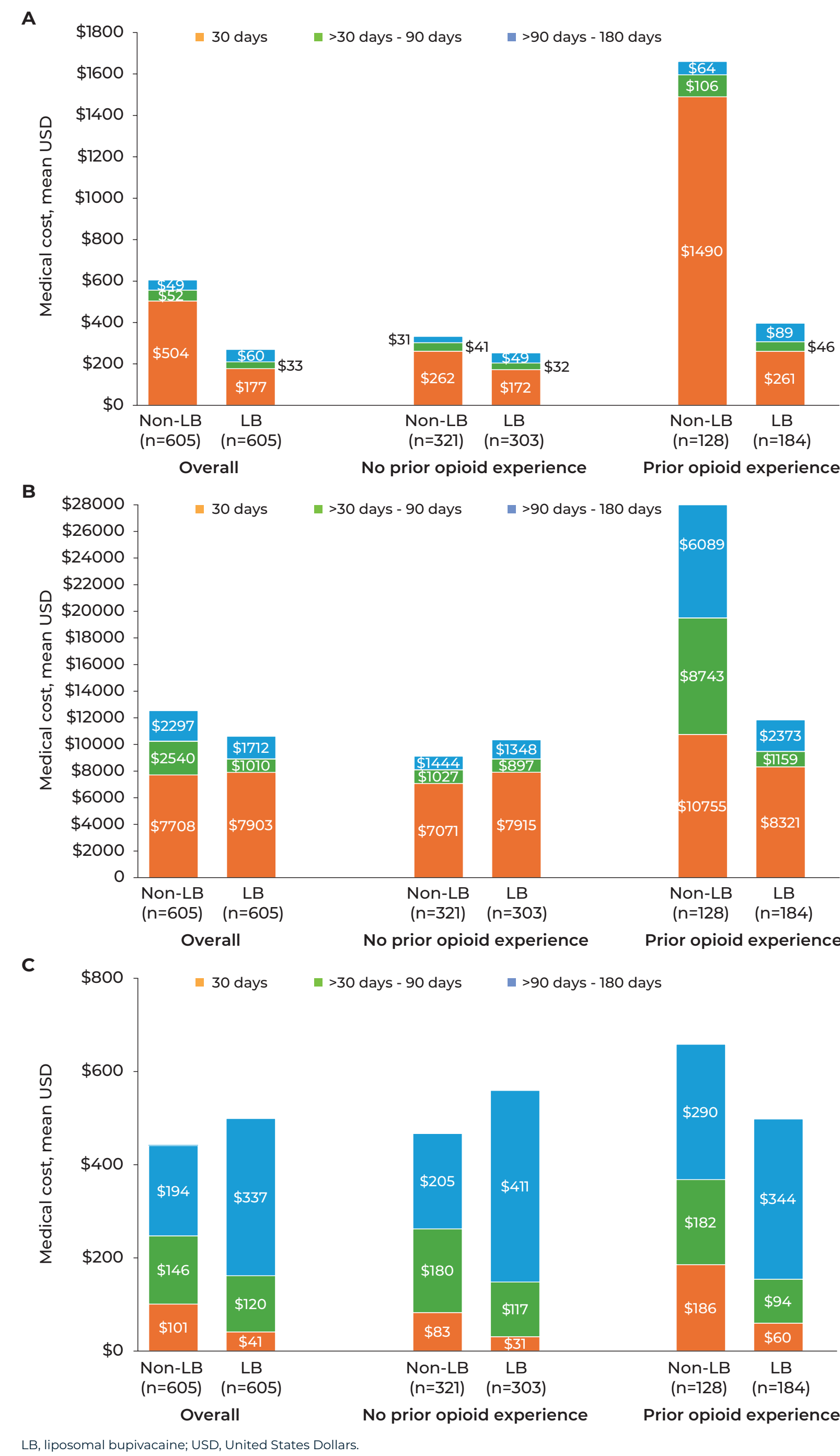


LB, liposomal bupivacaine; USD, United States Dollars.

## ENDPOINTS AND STATISTICAL ANALYSIS

- The main outcomes of the study included
  - Postsurgical cumulative opioid intake, reported as morphine milligram equivalents (MMEs), measured during the first week, 30 days, 90 days, and 180 days after surgery
  - All-cause total costs (ie, total medical episode-of-care cost) measured from admission to 30 days, 90 days, and 120 days after discharge
    - Individual cost categories include inpatient admissions, outpatient/office visits, and emergency department visits
  - Pharmacy costs measured from index to 30 days, 90 days, and 120 days after discharge
- Comparisons of outcomes listed above were performed via finite mixture regression modeling with gamma (medical costs) and zero-inflated negative binomial (MMEs, pharmacy costs) distributions
  - Subgroup analysis of outcomes was conducted by prior opioid exposure (defined as any opioid prescription with 6 months to 1 week before index surgery)

**Figure 3. (A) Inpatient, (B) outpatient, and (C) emergency department costs at the 30-day, 90-day, and 180-day follow-up since admission for LB and non-LB cohorts.**

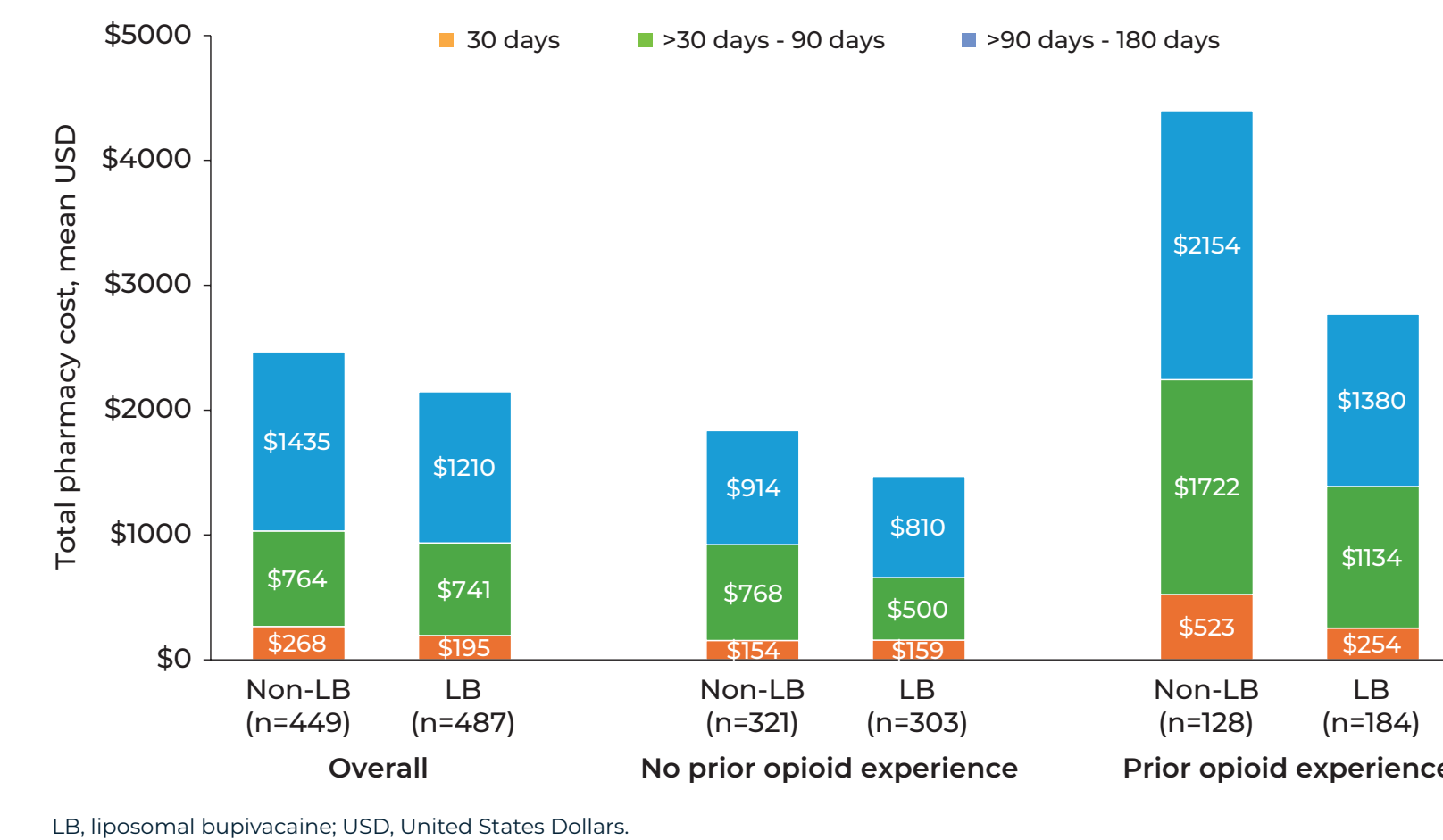


LB, liposomal bupivacaine; USD, United States Dollars.

## PHARMACY COSTS

- Lower pharmacy costs during the first 30 days after discharge were observed for the LB versus non-LB cohort (\$268 vs \$195;  $P=0.01$ ), with savings attributable to patients with prior opioid exposure (\$269 savings with LB;  $P<0.001$ ) (Figure 4)

**Figure 4. Total pharmacy costs at the 30-day, 90-day, and 180-day follow-up since admission for LB and non-LB cohorts.**



LB, liposomal bupivacaine; USD, United States Dollars.

## ANALYSIS AND DISCUSSION

- Medicare Fee-for-Service beneficiaries receiving postsurgical LB analgesia for outpatient bunionectomy had lower opioid intake than those receiving non-LB analgesia during the first 30 days of follow-up
- All-cause total healthcare costs were lower with LB over 180 days since surgery, with cost savings in the LB cohort attributable to inpatient and outpatient costs, followed by emergency department costs
- More pronounced medical and pharmacy cost savings were seen among patients with prior opioid exposure (a population who may be particularly vulnerable to higher healthcare expenditure)
  - Notably, more patients with prior opioid exposure reported chronic pain than those without prior exposure (30% and 18%, respectively), underscoring the importance of effective surgical recovery in this patient group and suggesting that the use of LB could potentially reduce the economic and clinical burdens in these patients following surgery
- Potential limitations of this study include its retrospective study design, that opioid use was measured not by intake but by the number of filled prescriptions, the lack of generalizability of the elderly patient population, and the possibility for incomplete direct clinical information from claims database (eg, lacking sciatic nerve blocks, field blocks, or other pain management procedures or regimens)
- Overall, these real-world data support the cost-effective use of LB as part of multimodal pain management for outpatient foot and ankle surgery