

# Economic Burden of Newly Diagnosed Patients with Plantar Fibromatosis (PF) in the United States (US)

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## INTRODUCTION

- Plantar fibromatosis (PF), also known as Ledderhose disease, is a rare condition involving the plantar aponeurosis resulting in disordered fibrous tissue and characterized by formation of nodules on the foot/feet.<sup>1</sup>
- In the current literature, there are no large studies examining healthcare resource utilization (HCRU) and costs among patients with PF in the US.
- To fill this critical research gap, our study examined the economic burden of PF in the US.

## OBJECTIVE

- This study described HCRU and healthcare costs among newly diagnosed patients with PF in the US.

## METHODS

### Data sources

- This retrospective study used data from IQVIA PharMetrics® Plus, a commercial health plan claims database, linked to IQVIA Ambulatory Electronic Medical Records – US (AEMR) between January 1, 2014 to March 31, 2022.
- Both databases are compliant with the Health Insurance Portability and Accountability Act (HIPAA) to protect patient privacy.

### Patient selection

- Eligible adult (≥18 years) patients with ≥1 diagnosis code for plantar fasciitis (ICD-9 782.71 or ICD-10 M72.2) in PharMetrics Plus were identified between January 1, 2015 and March 31, 2020.

- Given these ICD-9/10 diagnosis codes are used for PF and plantar fasciitis, AEMR was used to confirm PF diagnosis, using Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT) or problem names (Figure 1). SNOMED CT is a comprehensive health terminology that enables clinicians to capture clinical detail.<sup>2</sup>

- The earliest evidence of PF in PharMetrics Plus or AEMR was termed as the index date.

### Study measures

- Demographics were described using data on the index date. Baseline clinical characteristics and all-cause HCRU and healthcare costs were described during 12-month baseline.

- All-cause and PF-related HCRU and costs were reported for the 24-month follow-up, as well as separately for years 1 and 2 of the follow-up period.

- PF-related HCRU and costs were identified using claims with a PF diagnosis code or PF-related treatments.<sup>3-8</sup>

- Costs were converted to 2021 USD using the medical component of the Consumer Price Index.

- Partial and radical plantar fasciectomy costs were reported using all services on the surgery date, including the surgery, injectable pain medications, anesthesia, and other costs.

## RESULTS

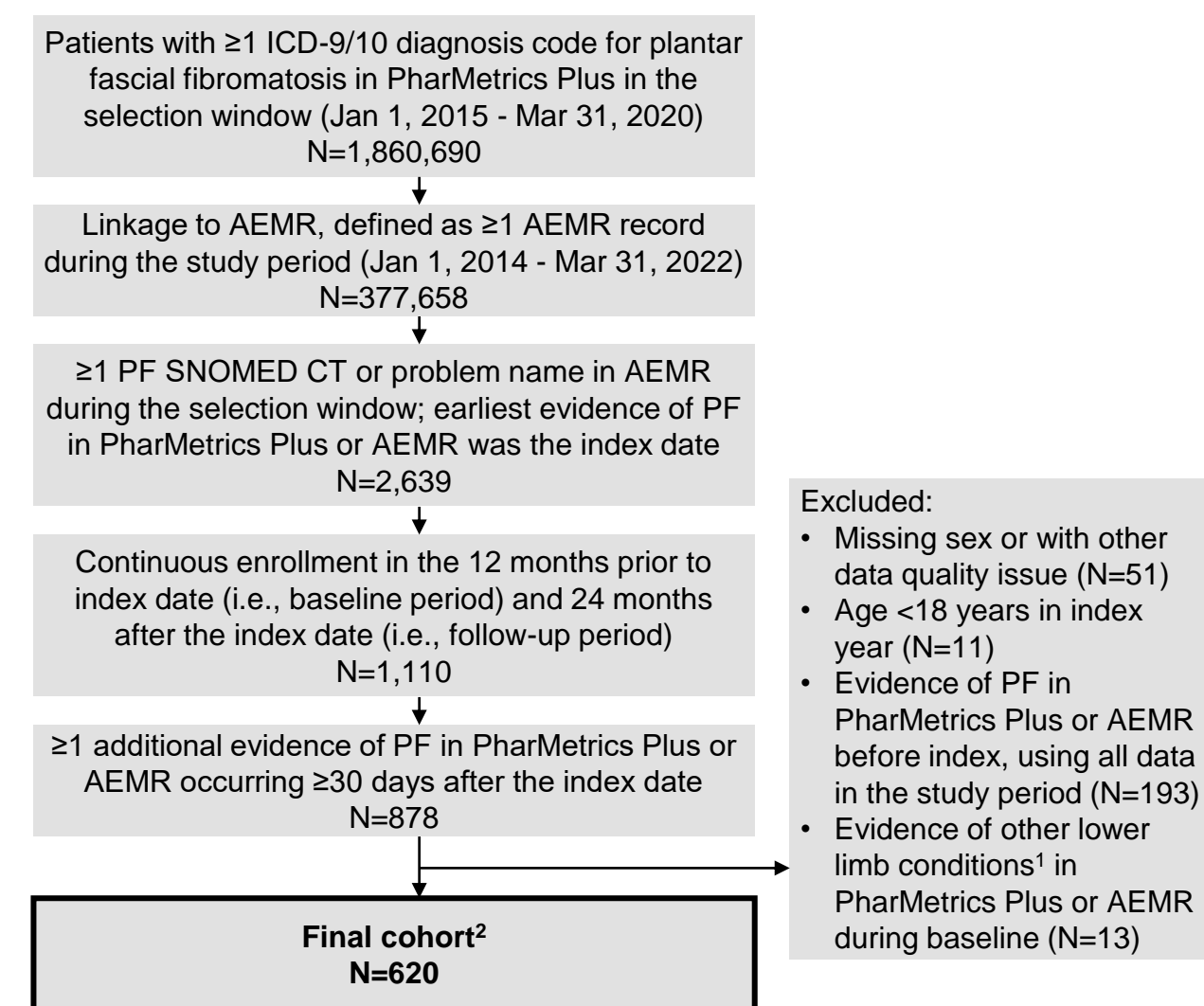
### Study cohort

- In total, 620 patients met all study selection criteria (Figure 1).

### Baseline characteristics

- The study cohort had a mean (SD) age of 52.2 (9.9) years.
- The cohort was predominantly female (63.2%); 36.8% were male (Table 1).

Figure 1. Selection of study cohort



- Lower limb conditions identified using diagnosis codes: benign neoplasm of connective and soft tissue, calcaneal fracture, calcaneal spur, fibrosarcoma, malignant neoplasm of connective and soft tissue, neuromiomas, rheumatoid nodules, or tarsal tunnel syndrome.
- There were no patients in the final cohort with evidence of plantar fasciitis in AEMR, based on SNOMED CT or problem name.

Table 1. Demographic and baseline clinical characteristics

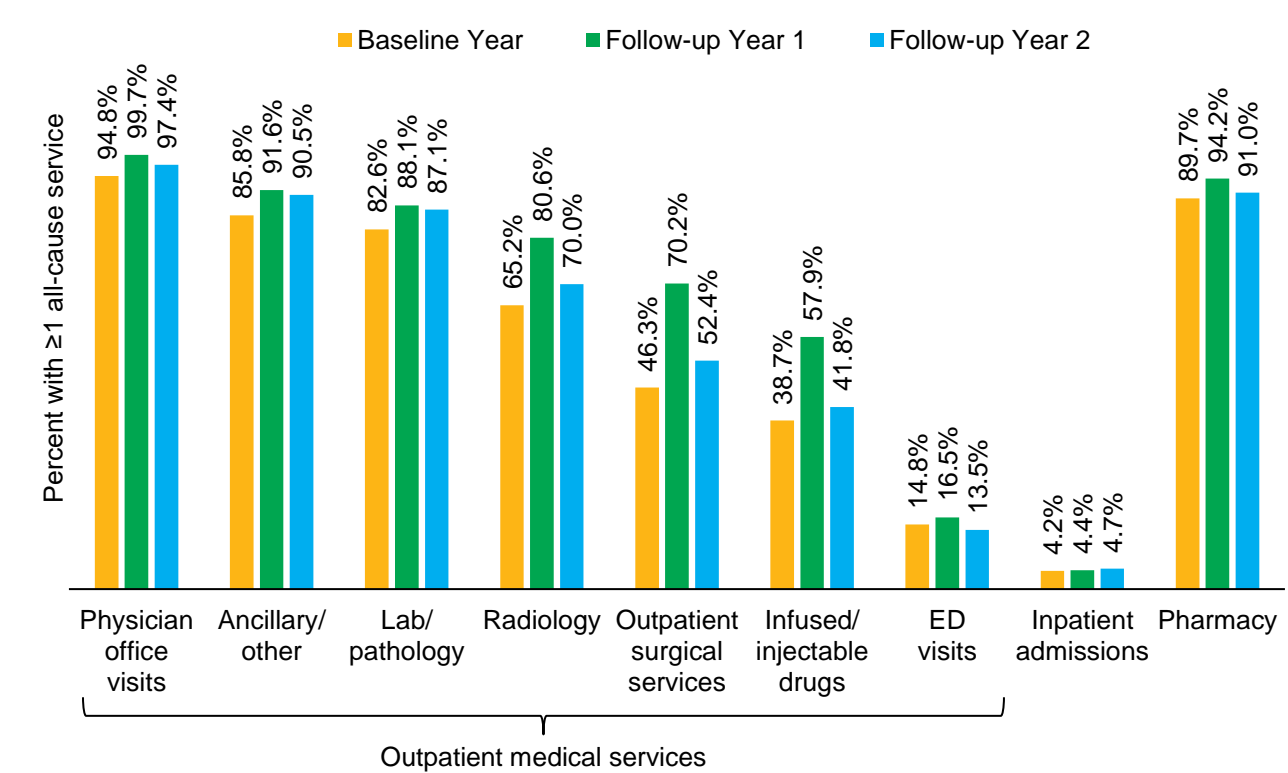
Measures	Incident PF cohort N=620
<b>Age at index (years)</b>	Mean (SD) 52.2 (9.9) Median (Q1, Q3) 53 (47, 59)
<b>Sex, n (%)</b>	Female 392 (63.2%) Male 228 (36.8%)
<b>Geographic region, n (%)</b>	Midwest 299 (48.2%) South 183 (29.5%) Northeast 102 (16.5%) West 36 (5.8%)
<b>Quan-Charlson comorbidity index (CCI) score, n (%)</b>	0 432 (69.7%) 1 94 (15.2%) 2 54 (8.7%) ≥3 40 (6.5%)
<b>Specific comorbidities, n (%)</b>	Thyroid disease 88 (14.2%) Diabetes without complications 76 (12.3%) Smoking <sup>1</sup> 76 (12.3%) Chronic pulmonary disease 69 (11.1%) Any malignancy 32 (5.2%)
<b>Baseline foot/ankle pain or stiffness, n (%)</b>	118 (19.0%)

1. Due to expected underreporting of smoking in claims data via ICD-9/10 diagnosis codes, smoking was assessed using data from both PharMetrics Plus and AEMR. All other measures were assessed using PharMetrics Plus only.

### All-cause HCRU

- The proportion of patients with ≥1 claim for all-cause HCRU within each utilization category was higher during year 1 and year 2 of follow-up compared with the 12-month baseline period (Figure 2).
- Physician office visits were the most common healthcare service used during baseline and follow-up periods.

Figure 2. Proportion of PF patients with ≥1 all-cause healthcare service during the baseline and follow-up periods

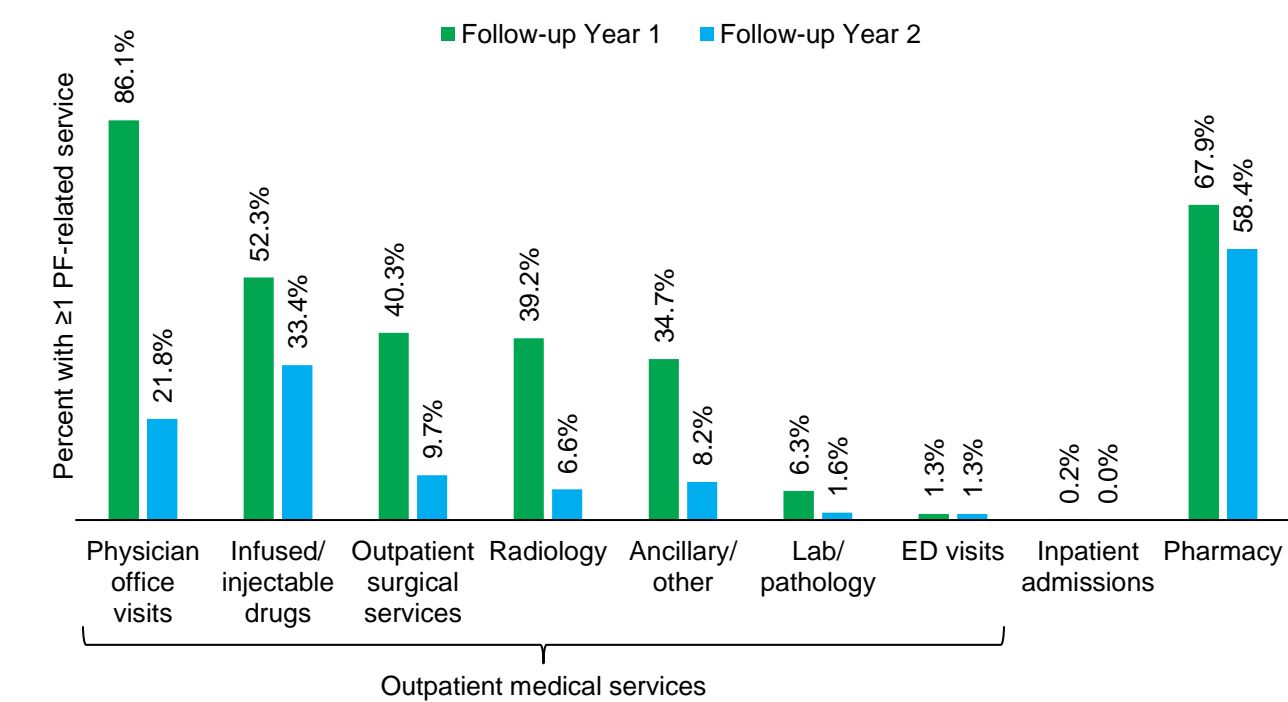


Abbreviation: ED, emergency department. Healthcare service categories include outpatient medical (subgroups shown in figure), inpatient, and outpatient pharmacy.

### PF-related HCRU

- The proportion of patients with PF-related HCRU declined from year 1 to year 2 of follow-up for nearly all utilization categories (Figure 3).
- Among the more common utilization categories, the decrease in the proportion of patients with ≥1 PF-related pharmacy service was relatively smaller.

Figure 3. Proportion of PF patients with ≥1 PF-related healthcare service during the follow-up period

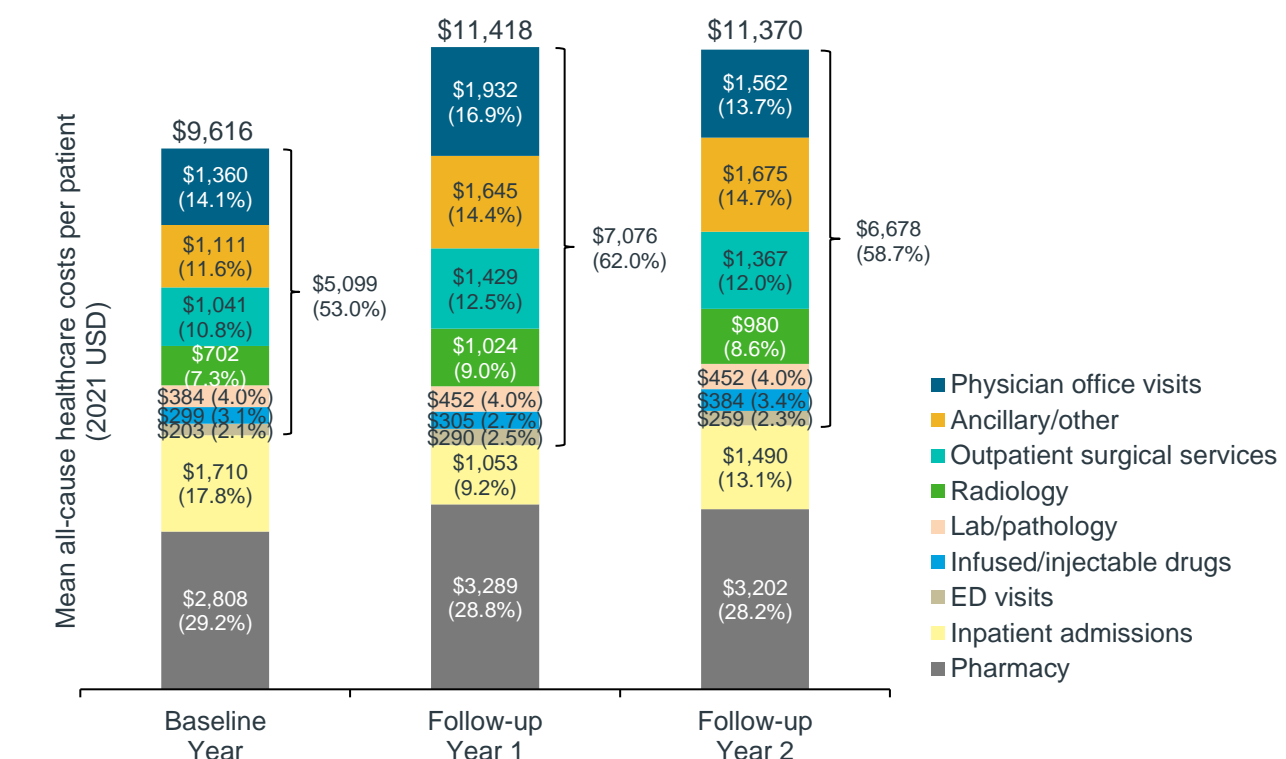


Abbreviation: ED, emergency department. Healthcare service categories include outpatient medical (subgroups shown in figure), inpatient, and outpatient pharmacy.

### All-cause healthcare costs

- Compared to the baseline year, the mean total all-cause costs per patient were 18.7% higher in follow-up year 1 and 18.2% higher in follow-up year 2 (Figure 4).
- During follow-up year 1, outpatient medical services accounted for the highest proportion of mean total all-cause costs (62.0%).

Figure 4. Mean all-cause healthcare costs per PF patient during the baseline and follow-up periods, by service category

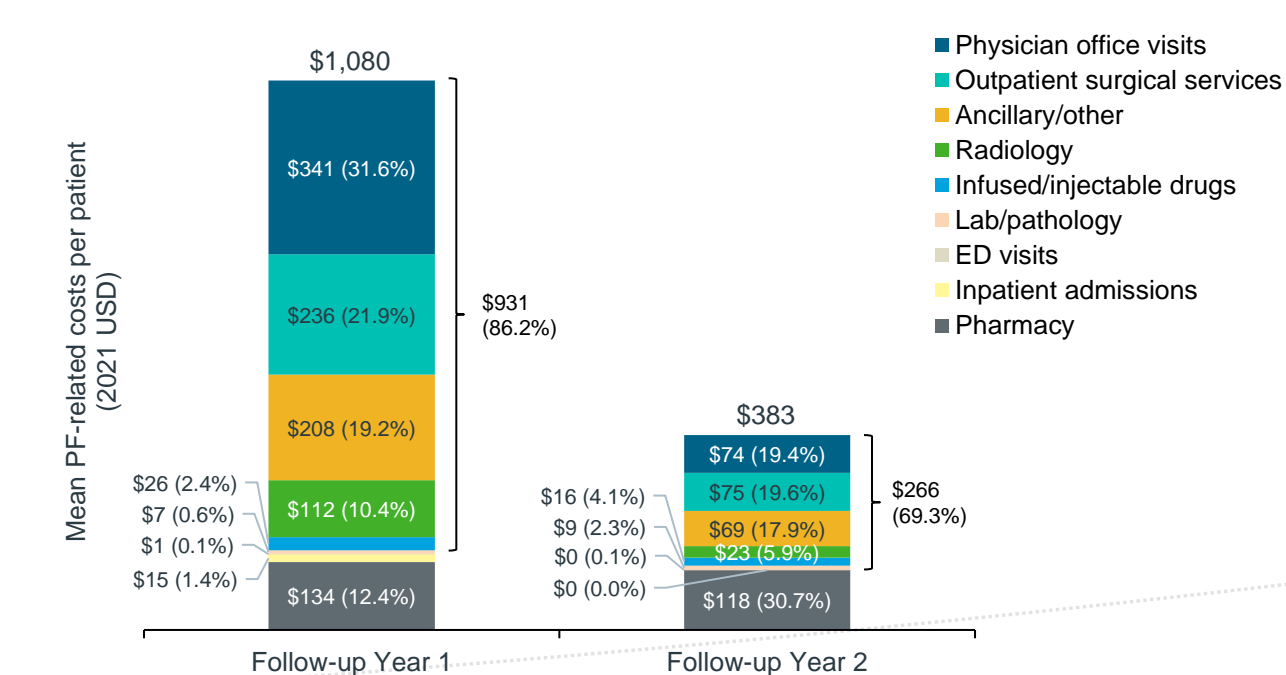


Abbreviation: ED, emergency department.

### PF-related healthcare costs

- The mean (SD) total PF-related cost per patient was \$1,463 (\$2,877) during 24-month follow-up, accounting for 6.4% of mean total all-cause costs (Figure 5).
- The mean (SD) total PF-related cost during follow-up year 1 (\$1,080 [\$2,223]) was nearly three times the mean cost during year 2 (\$383 [\$1,377]).
- Physician office visits and outpatient surgical service costs accounted for the largest sources of PF-related outpatient medical costs during both follow-up years.

Figure 5. Mean PF-related healthcare costs per patient during follow-up, by service category



Abbreviation: ED, emergency department.

### PF-related outpatient surgery costs

- Among 11 patients (1.8%) undergoing partial plantar fasciectomy, the mean (SD) total surgery costs were \$5,715 (\$3,915) per patient (median [Q1, Q3], \$4,681 [\$2,364, \$8,006]); 27.3% of mean costs were out-of-pocket costs.
- Among four patients (0.6%) undergoing radical plantar fasciectomy, the mean (SD) total surgery costs were \$7,781 (\$5,767) per patient (median [Q1, Q3], \$8,168 [\$2,874, \$12,688]); 13.4% of mean costs were out-of-pocket costs.

## LIMITATIONS

- Limitations inherent to administrative claims database studies include potential misclassification of PF, underreporting of comorbidities, and data entry error.
- Since the presence of SNOMED CT is dependent on the provider's EMR system, the patients with SNOMED CT in this study may represent a unique subgroup of PF patients.
- PharMetrics Plus has data predominantly from commercial health plans with limited capture of Medicare Parts A and B. However, since PF is most prevalent in adults aged 40-65 years,<sup>1</sup> it is expected that the findings from this study are generalizable to PF patients overall.

## CONCLUSIONS

- This study uniquely leveraged a claims database linked to EMR to identify patients with a rare disease that lacks a specific ICD-9/10 diagnosis code and fills a gap in the current literature regarding real-world HCRU and costs among newly diagnosed PF patients.
- Patients with PF had increased all-cause and disease-related HCRU and costs during the first year following diagnosis.
- PF-related costs were driven by outpatient medical services, including physician office visits and surgical services.
- While previous studies reported PF is more common in men,<sup>1</sup> this real-world cohort was predominantly women; future epidemiological studies with recent data are needed.

## REFERENCES

- Young JR et al. Orthop Res Rev. 2018 Dec 17;11:1-7.
- Mason C. J AHIMA 89, no. 8 (September 2018): 48-50.
- Carroll P et al. Foot Ankle Spec. 2018 Apr;11(2):168-176.
- Veith NT et al. Foot Ankle Int. 2013 Dec;34(12):1742-6.
- S SS et al. J Orthop Case Rep. 2019;9(2):84-86.
- Grenfell S, Borg M. J Med Imaging Radiat Oncol. 2014 Oct;58(5):641-7.
- Hammoudeh ZS. Plast Reconstr Surg. 2014 Sep;134(3):497e-499e.
- Lehrman JD et al. J Foot Ankle Surg. 2019 Nov;58(6):1281-1284.

## DISCLOSURES

RD, AN, JT, and EW are employees of IQVIA, which received funding from Endo Pharmaceuticals to conduct these analyses. JD, LD, DH, and LO are employees of Endo Pharmaceuticals. DA receives research support from the National Institutes of Health, the National Science Foundation, and Endo Pharmaceuticals.