

## **Using Appeals Data To Identify Policy Changes: Case Study of Lidoderm/Lidocaine and the Opioid Crisis**

In 2016, the Part D Qualified Independent Contractor (QIC) (or Independent Review Entity) processed 35,414 appeals related to non-formulary status, prior authorization, step therapy or quantity limits. Because the QIC reconsiders the redeterminations of all Part D plan sponsors across the country, the data the QIC generates is useful to notice nationwide trends that could be addressed through policy changes and reduce the number of Part D appeals.

For instance, data from the QIC shows that Lidoderm/Lidocaine has been the most commonly appealed drug for the past five years:

- 2013: 878 appeals;<sup>i</sup>
- 2014: 1,039 appeals;
- 2015: 5,218 appeals;
- 2016: 2,780 appeals;
- 2017: 1,819 appeals.

Lidocaine is a commonly used local anesthetic that produces pain relief when applied to the skin. For example, there is evidence that the Lidocaine is effective for lower back pain<sup>ii, iii</sup> and osteoarthritis.<sup>iv, v</sup> When considering alternative prescriptions to treat pain that do not have addictive qualities, some physicians will prescribe Lidocaine or the brand name Lidoderm 5% Patch.

Part D sponsors ensure<sup>vi</sup> that covered Part D drugs are prescribed for medically-accepted indications using the tools, data, FDA approval or any of three statutorily designated compendia.<sup>vii</sup> Thus, under current rules, the Part D plan sponsors only cover the Lidocaine Patch 5% for diabetic neuropathy or postherpetic neuralgia (a complication of shingles). When prescribed for another indication, the Part D plan sponsor will deny coverage. The beneficiary can request an appeal to the Part D QIC but it is denied on the same grounds.

In light of the opioid crisis, an analysis of the QIC appeals data, reconsideration files and medical records could provide evidence for a policy change that would allow physicians seeking a non-opioid pain reliever to prescribe Lidocaine. For instance, this policy change could help new Medicare beneficiaries that had Lidocaine covered under their previous commercial insurer to control chronic pain. Additionally, the change would help beneficiaries who have a temporary need for pain relief for an acute incident without risking opioid addiction

This is one example of how the reconsideration data of the QIC can be used to refine Medicare policy, reduce the number of appeals and improve the care options for beneficiaries.

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<sup>i</sup>For comparison, in 2013 Cialis, for treating erectile dysfunction, was second with 447 appeals; in 2014 Cialis was second with 558 appeals; in 2015, Zolpidem Tartrate (Ambien), for short-term treatment of insomnia, was second with 922 appeals; in 2016, Cialis was second with 791 appeals; in 2017, Mycophenolate Mofetil, an immunosuppressant drug used to prevent rejection in organ transplantation, was second with 1,202 appeals.

<sup>ii</sup> Gimbel J, Linn R, Hale M, Nicholson B. Lidocaine patch treatment in patients with low back pain: results of an open-label, nonrandomized pilot study. *Am J Ther.* 2005;12: 311-319.

<sup>iii</sup> Chou R, Qaseem A, Snow V, et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Ann Intern Med.* 2007;147: 478-491

<sup>iv</sup> Hochberg MC, Altman RD, April KT, et al. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. *Arthritis Care Res.* 2012; 64:465-474.

<sup>v</sup> Burch F, Codding C, Patel N, Sheldon E. Lidocaine patch 5% improves pain, stiffness, and physical function in osteoarthritis pain patients. *Osteoarthritis Cartilage.* 2004;12(3):253-255.

<sup>vi</sup> Medicare Prescription Drug Benefits Manual. <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>. Accessed May 10, 2018

<sup>vii</sup> FDA approval or any of three Compendia, identified at Section 1927(g)(1)(B)(i) of the Social Security Act: (1) American Hospital Formulary Service Drug Information; (2) United States Pharmacopeia-Drug Information (or its successor publications); or (3) DRUGDEX Information System.