DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR PROGRAM INTEGRITY

Investigations and Audits Group

Date: June 26, 2024

To: All Medicare Advantage Organizations (MAOs) and Prescription Drug Plan Sponsors (PDPs)

From: Sherri G. McQueen, Group Director
Fraud Investigations Group, Center for Program Integrity

Re: *Alert*: Santyl

The Centers for Medicare & Medicaid Services (CMS), in collaboration with the Investigations Medicare Drug Integrity Contractor (I-MEDIC), have become aware of a potential issue in the Medicare Part D program related to Santyl prescription drug event (PDE) records. This alert serves as notification to all plan sponsors of potential inappropriate billing of the drug Santyl.

Santyl is a Food and Drug Administration-approved prescription medicine that removes dead tissue from wounds. The I-MEDIC has received complaints from plan sponsors regarding excessive pharmacy billing of Santyl, typically involving inventory shortages at a subject pharmacy. I-MEDIC review of Medicare Part D PDE records of Santyl nationwide indicate that problematic pharmacies may be adding refills or quantities beyond what is medically necessary for the beneficiary. It is important for plans to know that pharmacies may bill Santyl for beneficiaries in long term care settings, who are being seen by wound care or other applicable specialists.

During the I-MEDIC review, the pharmacies' overall volume of Santyl dispensed was very high, but individual prescribers and beneficiaries did not stand out. The I-MEDIC review found beneficiaries with quantities that appeared excessive or that continued for longer than expected durations of time, but these were not associated with the complaint pharmacies and appeared to be potential waste or dispensing errors.

It is important to consider a pharmacy's overall dispensing pattern of Santyl to determine if an issue exists. A pharmacy which is an overall outlier may warrant further review and prescriber verification of dispensed amounts. Sponsors may also consider utilization-management edits to proactively limit amounts dispensed and duration of treatment, with additional volumes and duration upon submission of medical information.

The I-MEDIC recognizes that the need for wound care treatment can vary by individual beneficiary, and utilization review should rely on factors such as number of wounds, size and depth of wounds, and risk factors affecting potential treatment and healing. Although a calculator is provided on the manufacturer webpage[1], it is important not to solely rely on such tools to determine if a longer duration and volume of dispensing is suspected or medically necessary. Medical review, including pictures of wounds and wound care plans, may be needed to further specific investigations. Prescriber verifications of amounts/duration and wound care plans may also assist in determining if suspect pharmacies are inflating prescribed amounts.

CMS and the I-MEDIC are using this alert to provide plan sponsors with the details of the utilization of this drug to aid your compliance programs in the monitoring of potentially inappropriate PDE records in accordance with Chapter 9 of the *Prescription Drug Benefit Manual* and Chapter 21 of the *Medicare Managed Care Manual*.[2]

Please report your vetted complaints to CMS and the I-MEDIC by using the Health Plan Management System Program Integrity portal. If your organization has questions on this matter, please contact Bill Roland of the I-MEDIC at rolandb@qlarant.com.

[1] Collagenase SANTYL https://santyl.com Accessed June 18, 2024.

[2] *Medicare Managed Care Manual*, Chapter 21, and *Prescription Drug Benefit Manual*, Chapter 9: Compliance Program Guidelines. https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/chapter9.pdf Accessed June 20, 2024.