DEPARTMENT OF HEALTH & HUMAN SERVICES
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Audits and Vulnerabilities Group

Date: February 28, 2023

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

From: Jennifer Dupee, Director, Audits and Vulnerabilities Group

Subject: Completion of National Audit: Analysis of Prescription Drug Event Records for Nuedexta for Beneficiaries without a Medically Accepted Indication

The Centers for Medicare & Medicaid Services (CMS), in collaboration with the Plan Program Integrity Medicare Drug Integrity Contractor (PPI MEDIC), conducted a National Audit of Medicare Part D Payments for Nuedexta prescribed without a documented medically accepted indication (MAI) under the Medicare Part A, Part B, or Part C programs. The purpose of this notification is to inform all plan sponsors of the completion of the Nuedexta National Audit and to educate on CMS observations during the audit. Plan sponsors selected for the Nuedexta National Audit received notices with the results specific to their organization.

Background

In general, a Medicare Part D drug is defined as a drug that may be dispensed only upon a prescription and is used for an MAI. To be eligible for coverage under Medicare Part D, section 1860D-2(e)(4) of the Social Security Act (the Act) limits the MAI for a Part D drug by referencing section 1927(k)(6) of the Act, which requires the use of the drug to be approved under the Federal Food, Drug, and Cosmetic Act or supported by one of the compendia described in section 1927(g)(1)(B)(i) of the Act.[1]

The CMS-recognized compendia include the following:

- American Hospital Formulary Service Drug Information
- DRUGDEX® Information System

[1] Centers for Medicare & Medicaid Services, US Department of Health & Human Service. Medically-Accepted Indication. In: *Medicare Prescription Drug Benefit Manual*. Chapter 6, Section 10.6. https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. Revised January 15, 2016. Effective January 15, 2016. Accessed September 20, 2022.

As a result, drugs prescribed to beneficiaries for purposes other than an MAI are not eligible for coverage under Medicare Part D. Medicare Part D plan sponsors are responsible for ensuring that covered Part D drugs are prescribed for an MAI using the tools and data available to them, such as utilization management edits and the CMS-recognized compendia to make such coverage determinations.[2]

Nuedexta is a prescription drug approved by the U.S. Food and Drug Administration (FDA) for the treatment of pseudobulbar affect (PBA) disorder. PBA disorder, also referred to as emotional lability or emotional incontinence, is a neurological condition characterized by outbursts of uncontrolled laughter or crying seemingly unrelated to mood.[3] Although the term "emotional lability" is used along with PBA, the FDA labeling indicates that "PBA is a specific condition, distinct from other types of emotional lability that may occur in patients with neurological disease or injury."[4] The disorder typically occurs in people with neurological conditions or injuries such as stroke, amyotrophic lateral sclerosis (ALS), traumatic brain injury (TBI), multiple sclerosis (MS), Alzheimer's disease, and Parkinson's disease. The FDA has also designated Nuedexta as an orphan drug for the treatment of ALS.

The Nuedexta National Audit was initiated to address the historical concerns of fraud, waste, and abuse associated with this drug, in addition to the significant potential risks of beneficiary harm if the use of Nuedexta is not clinically supported. The use of Nuedexta has been associated with inappropriate prescribing for beneficiaries in long-term care facilities. In September 2019, the U.S. Department of Justice (DOJ) announced that Avanir, the manufacturer of Nuedexta, agreed to pay over $95 million to resolve allegations of kickbacks as well as false and misleading marketing of Nuedexta for purposes other than an MAI to providers in long-term care facilities.[5]

Audit Results and Observations

The Nuedexta National Audit included prescription drug event (PDE) records from January 1, 2019, through December 31, 2020. As part of the National Audit process, selected plan sponsors were required to submit supporting documentation for PDE records they considered to be proper. CMS reviewed all documentation provided to validate whether the plan sponsors' determinations were proper. For the Nuedexta National Audit, CMS agreed with most of the proper determinations made by plan sponsors that required prior authorization for drug coverage.

For those PDE records deemed improper, CMS directed plan sponsors to assess the process and control issues that resulted in the submission of improper payments under the Medicare Part D

[2] Ibid.
[3] Nuedexta (dextromethorphan hydrobromide/quinidine sulfate) in DRUGDEX® System [database online]. Greenwood Village, CO: Truven Health Analytics. http://www.micromedexsolutions.com. Accessed September 20, 2022.
[4] NUEDEXTA® [package insert] Aliso Viejo, CA: Avanir Pharmaceuticals, Inc; 2021
[5] Pharmaceutical Company Targeting Elderly Victims Admits to Paying Kickbacks, Resolves Related False Claims Act Violations. [news release] Civil Division - Northern District, GA: US Attorney's Office, US Dept. of Justice; September 26, 2019. https://www.justice.gov/opa/pr/pharmaceutical-company-targeting-elderly-victims-admits-paying-kickbacks-resolves-related. Accessed September 19, 2022.

program, and required plan sponsors to delete the improper PDE records. CMS expects this will allow plan sponsors to determine what corrections must be made to address these deficiencies and to evaluate and correct active prior authorizations that may be associated with improper payments or lead to future improper payments.

In response to previous CMS guidance issued to MAOs and PDPs, many plan sponsors strengthened prior authorization requirements for Nuedexta. However, despite the CMS education and plan sponsor response, CMS continues to see approved prior authorization requests for Nuedexta for purposes other than an MAI, such as dementia, pseudobulbar palsy, and emotional lability. Rather than clarify the intended use with the prescriber or deny the request based on the non-MAI use documented by the prescriber, several plan sponsors referenced historical information, such as medical claims history or information obtained from a previous request, to authorize the drug. Plan sponsors should apply caution when overriding information provided by the prescriber regarding the current intended drug use.

CMS also identified a few instances in which the documentation indicated the beneficiary was receiving hospice services and the drug use was hospice-related. Plan sponsors are responsible for complying with all Medicare Part C and Part D rules and regulations when making a coverage determination; therefore, all information provided on documentation submitted to plan sponsors should be carefully evaluated. A drug for which coverage is available under Part A, as being prescribed and dispensed or administered, is excluded from the definition of a Part D drug and, therefore, should not be paid under Part D.

Furthermore, several plan sponsors submitted incomplete documentation consisting of clipped sections of documentation rather than complete copies of the original documents, such as faxes and electronic PA requests. Additionally, a significant amount of submitted documentation did not contain the appropriate beneficiary identifiers to allow CMS to link the documentation to the PDE record being audited.

CMS encourages all plan sponsors, including those not directly selected for the National Audit, to evaluate its coverage of, and payments for, Nuedexta. This evaluation will vary among plan sponsors depending upon the formulary status and use of utilization management edits. CMS also recommends that plan sponsors evaluate the health and safety of the beneficiaries associated with those PDE records prescribed without an MAI. Additionally, plan sponsors should be conducting retrospective reviews and delete any identified improper payments.

If you have any questions related to this memo, please send your inquiry to CPIMedicarePartD_Data@cms.hhs.gov with “Nuedexta National Audit Findings 2022” in the subject line.