Improving Drug Utilization Review Controls in Part D

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Overview

- Background
- Explanation of Three “Levels” for Improving Drug Utilization Review Controls in Part D
- Pilot of “Level Three” (Improved Retrospective DUR Programming and Case Management)
- Morphine Equivalent Dose (MED)
- Questions

Background

- GAO Report, Sept. 6, 2011,"Medicare Part D, Instances of Questionable Access to Prescription Drugs"[4]
- In September 2011, CMS began working on an approach to help plans identify and manage the most egregious cases of opioid overutilization.
- Comprehensive policy was set forth in draft and final Call Letter (April 2012) and in more detail in draft and final supplemental guidance (June 2012 and August 2012)

[4]GAO-11-699. (Washington, D.C.: Sept. 6, 2011).

Explanation of Three "Levels" for Improving Drug Utilization Review Controls in Part D

- Level One: Improved Use of Concurrent Claim Edits (Safety Controls at POS)
  - Part D sponsors expected to prevent coverage of unsafe daily doses of acetaminophen (APAP)
  - Maximum dose is 4 gm/day as recommended by FDA
- Level Two: Improved Use of Formulary Management Designs (Quantity Limits at POS)
  - Part D sponsors may also submit QLs to CMS for approval when no FDA maximum dose (e.g., most opioid analgesics) or below FDA maximum dose

"Level Three": Improved Retrospective DUR Programming & Case Management

- Part D sponsors should look for apparent duplicative opioid drug use over sustained periods of time and/or across multiple opioid drug products in high doses
- Clinical staff to communicate with prescribers to ascertain medical necessity (August 31 guidance provides sample letters)
- Communication to include information about the existence of multiple prescribers and the beneficiary's total opioid utilization
- Results of case management to confirm: 1) current level of opioids; 2) lower level of opioids; or 3) no opioids

"Level Three": Improved Retrospective DUR Programming & Case Management

- No status quo if prescribers are non-responsive and MEDIC referrals as appropriate
- Part D sponsors to determine appropriate claim edit for beneficiary where current level is not confirmed to be medically necessary
- Examples of claim edits are: a) ones allowing a certain daily morphine equivalent dose (MED) or specific opioids and quantities, or b) a prior authorization requirement on every future opioid
- Part D sponsors must provide 30-day advance written notice to beneficiary and opioid prescriber(s) of pending POS edit with the right to contest.
- Lock-in to specific prescribers or pharmacies is not permitted in the Part D program.
- CMS will monitor Part D sponsors' implementation.

Case Management Pilot
Overview

- Purpose
  - Implement Level Three as described in draft June 29 guidance
  - Inform final guidance released on August 31
- Timeframe: June 14 to August 13
- Participants: CVS/Caremark, Humana, United HealthCare
- Monitoring: Weekly calls with each sponsor and CMS

Case Management Pilot
What We Learned

- Case management approach is effective to address the most difficult cases of potential opioid overutilization.
- There is flexibility of approach within CMS guidance.
- Approach can be implemented in less than 90 days.
- Cases are complex, requiring investigation beyond the obvious facts.

Case Management Pilot
What We Learned

- Sample prescriber letters were revised to be more neutral; initial beneficiary inquiry letter was eliminated.
- There were three categories of prescriber response:
  - Agreement on opioid usage problem and cooperation with case management
  - Assertion that opioid usage is appropriate and being managed
  - Lack of response or no prescriber willing to manage the patient

Morphine Equivalent Dose (MED)
Purpose

- During pilot, CMS simultaneously looked for a method to:
  - Assess potential patient safety risks due to overutilization based upon latest research
  - Identify a manageable target population of high opioid users for case management with minimal false positives
- CMS determined that MED methodology is a useful tool to assess and manage risks associated with use of opioids.[5,6]

[5]Dunn KM, Saunders KW, Rutter CM, Banta-Green CJ, Merrill JO, Sullivan MD, Weisner CM, Silverberg MJ, Campbell CI, Psaty BM, Von Korff M. Opioid prescriptions for chronic pain and overdose: a cohort study. *Ann Intern Med* 2010;152(2):85-92.
[6]Washington State Agency Medical Directors' Group, Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain: An educational aid to improve care and safety with opioid therapy, 2010 Update. Available at www.agencymeddirectors.wa.gov.

Morphine Equivalent Dose (MED)
Analysis

- Evaluated the scope of the population at risk, including prescribing and dispensing,
- Determined segments of Part D population that may be at-risk for dose-related adverse effects, and
- Developed a retrospective review methodology based on MED to share with Part D sponsors

Morphine Equivalent Dose (MED)
Findings

- CMS MED Analyses in Part D (2011 PDE)
  - Results, excluding cancer and hospice care:
    - 8.8 million (28%) opioid analgesic utilizers in Part D
    - 1.8 million (5.6%) exceeded 120 mg MED for at least one day
    - 225,000 (0.71%) exceeded 120 mg MED for at least 90 consecutive days
    - 22,222 (0.07%) also used more than 3 prescribers and more than 3 pharmacies during the 90-day period

QUESTIONS?