

Formulary Administration

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Operations

Formulary Administration Audit

- CMS will review P&T minutes and other documents to ensure compliance with P&T requirements.
- Rejected claims will be reviewed to identify where the sponsor failed to administer the approved benefit.
- PDEs will be reviewed versus the rejected claims to identify non-compliance with transition requirements.
- You will be required to run test claims so that CMS can ensure accurate formulary adjudication.

Failure to Utilize the Required Compendia

- Some Part D sponsors failed to utilize the compendia as defined by the Act.
 - Failure to use Drugdex, AHFS.
 - Inappropriate use of other sources (e.g., drugs.com).
- MIPPA change in the definition of medically accepted indication.
 - December 9, 2008 HPMS memo.
 - Sponsors failed to review the revised compendia.

Failure to Adjudicate the CMS-Approved Formulary

- Rejection of claims for covered Part D drugs.
- Imposition of unapproved utilization management (UM) edits.
 - Age restrictions not supported by the FDA-approved label.
 - Laboratory tests and medical procedures not included in the prior authorization (PA) criteria submitted to CMS.
 - High-cost edits resulting in clinical PAs that were not submitted to CMS.

Drugs within the Classes of Clinical Concern

- Anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection.
- PA and step therapy (ST) must be limited to beneficiaries who are just starting on the drug (no PA or ST allowed on antiretrovirals).
 - If a sponsor cannot determine at point of sale whether a beneficiary is a new start or not, the sponsor must treat the beneficiary as currently taking the drug.

Failure to Display Required Materials on Formulary Websites

- Sponsors have posted only an updated search tool but not an updated comprehensive formulary.
- Others failed to post PA and ST requirements.
- One sponsor posted unapproved PA and ST requirements.
- Sponsors have posted other formulary information that has differed from the CMS-approved formulary.

Avoiding Beneficiary Access Issues

- Review guidance and contact CMS with questions.
 - Chapter 6 of the Medicare Prescription Drug Benefit Manual
 - HPMS Part D Transition Policy Reminder Memo – August 27, 2010
- Perform close oversight of PBM and other entities.
- Provide for ample testing in advance of January 1:
 - Formulary changes across the contract year
 - Drugs within the classes of clinical concern
 - Proper coverage of other drugs
- Monitor CTM.