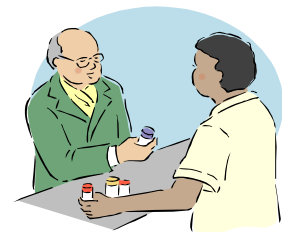


National Aging and the Law Conference

Medicare Part D: Exceptions and Appeals The Good, The Bad, and the Ugly

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The Part D Framework

- Decentralized and unstandardized
- Many plans – PDP and MA-PD
- Different and changing formularies
- Different tiering structures
- Different utilization management tools
- Different processes, forms, etc.

Denial of Drug Coverage

- At the pharmacy counter
 - Generic posted notice
 - No individualized written notice
 - Some info available to pharmacist
 - Assistance depends on pharmacist time/inclination
 - Denial is NOT a “coverage determination”



Reasons for Denial

- Not a Part D drug
 - Medicaid may cover for dual
 - Is drug on an enhanced plan? Can you change? Is it worth it?
- A Part B drug
 - Pharmacist can clarify with MD
- Not on formulary, wrong tier, utilization management
 - Is substitution OK with MD?
 - Can you change plans? On the Low Income Subsidy?
 - Are you in a transition period?

Coverage Determinations

- Decision re “payment or benefits to which an enrollee believes he or she is entitled.”
- Most denials at pharmacy are NOT Coverage Determinations
 - Prior Authorization denial is a coverage determination.
 - Other coverage determinations must be requested
- Types of coverage determinations
 - Exceptions—formulary, utilization mgmt, tiering
 - Other—Prior Auth, co-payments, out-of network pharmacy, etc

Coverage Determinations — Formulary Exception

- Why:
 - Obtain Rx not on plan's formulary
 - Get different dosage or form/avoid dosage restriction
 - Bypass Prior Auth, step therapy, therapeutic substitution requirement
 - Obtain Rx for off-label use
- If approved, plan can decide level of cost-sharing for non-formulary drugs
 - Plan cannot create new tier or put on special tier.

Formulary Exception—Legal Standard

Treating physician supporting statement must show medical necessity:

- All on-formulary drugs are not as effective or have adverse effects OR
- Dosage restriction i. has been ineffective or ii. is likely to be ineffective for this individual OR
- Substitute drug or step therapy required i. has been ineffective or is likely to be ineffective for this individual or ii. has caused adverse reaction or likely to do so.
- Based on clinical/medical evidence.
- MD statement to be accorded “great weight.”

Coverage Determinations — Off-Label Use

- Off-Label Use – a special case
 - Show medical necessity AND
 - Show use for a “medically accepted indication”
 - Use is FDA approved or
 - Use appears in a compendium
 - American Hospital Formulary Service Drug Information
 - United States Pharmacopoeia-Drug Information
 - DRUGDEX Information System
 - Peer reviewed articles are not sufficient
 - Note: Exceeding FDA dosage limits does NOT require compendium support

Coverage Determinations —Tiering Exceptions

- To obtain non-preferred drug at preferred prices
 - Lower cost, but not generic tier
 - Some high cost and unique drugs are not eligible for tiering exceptions (grievance, only)
- Doctor must show: “preferred drug is not as effective as requested drug OR has adverse effects”*
- Not relevant to Low Income Subsidy recipients
- Few tiering exceptions filed—under 2% of appeals

* Based on clinical/medical evidence



Coverage Determinations --- Procedures

- Not automatic
 - Beneficiary, authorized representative or prescribing physician must request.
 - Need physician supporting statement
- How to file
 - Call plan or go to website or EOB to find out.
 - Plans may have their own forms but must accept any form of written support from doctor (model form).
- How long does an exception extend
 - Approval lasts for plan year (plan can extend).
 - Prior Auth can be shorter.

Coverage Determinations--Timeframe

- Standard (72 hrs) and Expedited or “Fast” (24 hrs or as expeditiously as enrollee’s health requires).
- Getting expedited treatment
 - Doctor attests that standard timeframe may place “life, health or ability to regain maximum function in serious jeopardy.”
 - Plan must accept doctor’s attestation.
 - Not available if enrollee has paid for drugs



Coverage Determinations -- Timing

- Need physician supporting statement
 - Clock starts on receipt of MD statement
 - Can ask doctor for more info. Request does not stop the clock.
 - Plan cannot stop the clock with a temporary drug supply
- If approved:
 - Must provide drugs within the decision timeframe
 - Must provide refund within 30 days
- What if plans miss deadlines?
 - Must forward to IRE within 24 hours
 - Emergency drug supply until IRE decision

Appeals

- Five Levels

- **REDETERMINATION** by plan
- **RECONSIDERATION** by IRE (Maximus)
- **HEARING** by Administrative Law Judge
- **REVIEW** by Medicare Appeals Council
- **FEDERAL COURT**

- Not automatic – 60 days to file
- Expedited track available at redetermination and IRE levels

Appeals

- Level 1: Redetermination

- Another decision maker within the plan
- Standard: 7 days/Expedited : 72 hours
- Physician may file if expedited
- Limited success rate

Appeals

- Level 2: IRE Reconsideration

Written request to Independent Review Entity (Maximus) within 60 days of redetermination

- Standard: 7 days/Expedited: 72 hours
- Success rate: over 50%



Appeals

- Level 3: ALJ Appeal
 - Decided within 90 days – No expedited treatment
 - Medicare appeals processes apply:
 - videoconference hearings
 - Plan and/or Maximus participation

Appeal Procedures

- Level 4: Medicare Appeals Council
 - Decided within 90 days? —no expedited treatment
 - MAC can deny hearing
- Level 5: Federal District Court
 - Amount in Controversy
 - Must be at least \$1130 (2007), including projected amount the beneficiary would spend on drug during plan year

Last Thoughts

- Make it easy for the physician.
- Keep records of timing of all submissions.
- Keep appealing! Persistence pays.

Questions

Call with questions, problems, send client stories

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Resources

NSCLC Tools for Advocates

http://www.nslc.org/areas/medicare-part-d/area_folder.2006-09-28.4596471630/area_folder.2006-10-31.2079546039

- Medicare Part D Exceptions and Appeals, A Practical Guide (NSCLC)
- Exceptions and Appeals: Summary of Ch. 18 of the CMS Prescription Drug Benefit Manual (NSCLC)

CMS materials on NSCLC website

http://www.nslc.org/areas/medicare-part-d/area_folder.2006-09-28.5758698482/area_folder.2006-10-12.2240438420/area_folder.2006-10-12.1178089624

- Exceptions and Appeals: Model Part D: Exceptions/Coverage Determination Request Form (CMS)
- Medicare Prescription Drug Benefit Manual, Ch. 18 (Exceptions) and Chapter 6 (formulary and transitions)
- Maximus Reconsideration Procedures Manual

CMS web page on appeals: http://www.cms.hhs.gov/MedPrescriptDrugApplGriev/11_Guidance.asp

Model Coverage Determination Request form:

<http://www.cms.hhs.gov/MedPrescriptDrugApplGriev/Downloads/PhysicianCoverageDeterminationRequestForm.pdf>

Other Resources

- Appointment of Representative Form (CMS Form-1696):
<http://www.cms.hhs.gov/CMSForms/CMSForms/itemdetail.asp?filterType=keyword&filterValue=1696&filterByDID=0&sortByDID=1&sortOrder=ascending&itemID=CMS012207>
- Patient Assistance Programs (PAP): <http://www.rxhope.com>