Access to Pharmaceuticals in the Medicare Drug Benefit

Drugs and Pharmacies

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2007: Enrollment and Eligibility

- Annual Election Period for 2007
  - November 15 to December 31, 2006
  - No time between enrollment and January 1
  - Encourage early-in-month enrollments
- New Special Enrollment Period for LIS beneficiaries
- Facilitated enrollment May 1, 2006…special SEP to facilitate ongoing enrollment begins with notification of status (effective date is enrollment or if choice 1st of the month)
- LIS Outreach Campaign

2007: Formularies

- Changes in 2006
  - Must maintain beneficiary on current formulary drug if plan changes formulary (other than for safety reasons), not increase tier, or add “cost management mechanisms”.
- Changes in 2007
  - Mandatory coverage of 6 drug classes continues
  - Must make coverage decision within 90 days of market entry
  - Plans can use UM tools when starting therapy in all classes but HIV/AIDS
  - Only one specialty tier allowed (not subject to exceptions)– negotiated prices must exceed $500/month
- Part B and D coverage continues to be an issue
  - Need diagnosis code on Rx to help pharmacist determined whether to bill Part B or Part D

Appeals Process

- Step 1 – “Coverage Determination” (plan decision)
- Step 2 – Reconsideration by outside organization
- Step 3 – Hearing before ALJ
- Step 4 – Review by Medicare Appeals Council
- Step 5 – Federal District Court

Request for Prescription Information or Change

Medicare Prescription Drug Coverage

Provider Communication Form

TO: (Prescribing Physician):_____Date:_____

Fax:_____ Phone:_____

Patient Name:_____

Name of Drug Plan:_____ Phone (if available):_____

Member Number:_____ Prescription Number :_____

PRESCRIPTION ISSUES

☐ The patient's drug plan has indicated that it will not pay for _____ _____ for this patient because:

- ☐ Prior authorization required
- ☐ Step therapy required. Plan will pay for _____
- ☐ Plan only authorizes_____ dosage units (tablets/capsules) per prescription
- ☐ Plan does not pay for drug in dosage/format prescribed
- ☐ Drug is not on the formulary. NOTE:
  - ☐ Plan authorized one-time only payment for this drug
  - ☐ Plan did not authorize one-time payment
  - ☐ Other drugs on the formulary include (if available): _____ _____
- ☐ Other reason(s)_____

☐ The patient's drug plan covers this drug, but with a high tiered co-pay. Preferred drugs available at lower co-pay: _____

☐ ***ACTION REQUESTED – Please Respond To Pharmacy:***

Pharmacist Requesting Action:_____

- ☐ **Urgent - patient is waiting**
- ☐ By next refill:_____ (Date)
- ☐ Provide alternative medication: _____
- ☐ Other recommended action:_____

For Fax Back:
Physician Signature:_____ Date:_____

☐ ***ACTION REQUESTED – Please Contact Drug Plan:***

- ☐ Request prior authorization
- ☐ Request exception to formulary

☐ ***INFORMATION ONLY - No Immediate Action Necessary***

PLEASE NOTE: Medicare Part D does not pay for barbiturates, benzodiazepines, fertility drugs, drugs for weight loss or weight gain, drugs for hair growth, over-the-counter drugs, or prescription vitamins (except prenatal vitamins and fluoride preparations).

FROM: Pharmacy Name:_____

Fax:_____ Phone:_____ e-mail:_____

Address:_____ Phone: _____

Information on this form is protected health information and subject to all privacy and security regulations under HIPAA.
Use of this form is endorsed by the Alzheimer's Association, American Medical Association, American Pharmacists Association, Center for Medicare Advocacy, Medical Group Management Association, National Community Pharmacists Association and the National Council on the Aging

<Plan Logo>

<Plan Mailing Address>
<Plan Phone Number>
<Plan Fax Number>

Medicare Part D Coverage Determination Request Form

This form cannot be used to request:

- Medicare non-covered drugs, including barbiturates, benzodiazepines, fertility drugs, drugs prescribed for weight loss, weight gain or hair growth, over-the-counter drugs, or prescription vitamins (except prenatal vitamins and fluoride preparations).
- **Biotech or other specialty drugs for which drug-specific forms are required. [See <Part D plan website.>] OR [See links to plan websites at http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/04_Formulary.asp]**

Patient Information			**Prescriber Information**		
Patient Name:			Prescriber Name:		
Member ID#:			NPI# (if available):		
Address:			Address:		
City:	State:		City:		State:
Home Phone:	Zip:		Office Phone #:	Office Fax #:	Zip:
Sex (circle): M F	DOB:		Contact Person:		

Diagnosis and Medical Information		
Medication:	Strength and Route of Administration:	Frequency:
☐ New Prescription OR Date Therapy Initiated:	Expected Length of Therapy:	Qty:
Height/Weight:	Drug Allergies:	Diagnosis:
Prescriber's Signature:		Date:

Rationale for Exception Request or Prior Authorization
FORM CANNOT BE PROCESSED WITHOUT REQUIRED EXPLANATION

☐ Alternate drug(s) contraindicated or previously tried, but with adverse outcome (eg, toxicity, allergy, or therapeutic failure)
→ Specify below: (1) Drug(s) contraindicated or tried; (2) adverse outcome for each; (3) if therapeutic failure, length of therapy on each drug(s);

☐ Complex patient with one or more chronic conditions (including, for example, psychiatric condition, diabetes) is stable on current drug(s); high risk of significant adverse clinical outcome with medication change
→ Specify below: Anticipated significant adverse clinical outcome

☐ Medical need for different dosage form and/or higher dosage
→ Specify below: (1) Dosage form(s) and/or dosage(s) tried; (2) explain medical reason

☐ Request for formulary tier exception
→ Specify below: (1) Formulary or preferred drugs contraindicated or tried and failed, or tried and not as effective as requested drug; (2) if therapeutic failure, length of therapy on each drug and adverse outcome; (3) if not as effective, length of therapy on each drug and outcome

☐ Other:_____ → Explain below

REQUIRED EXPLANATION:_____
_____
_____

Request for Expedited Review

☐ REQUEST FOR EXPEDITED REVIEW [24 HOURS]
→ BY CHECKING THIS BOX AND SIGNING ABOVE, I CERTIFY THAT APPLYING THE 72 HOUR STANDARD REVIEW TIME FRAME MAY SERIOUSLY JEOPARDIZE THE LIFE OR HEALTH OF THE MEMBER OR THE MEMBER'S ABILITY TO REGAIN MAXIMUM FUNCTION

<HIPAA Disclaimer>

2007: Transition Guidance

- All PDP's have at least a 30 day transition supply for first 90 days of enrollment in plan – higher days supply and longer period for LTC
- Plans must provide notices to beneficiaries including:
  - Transition supply is temporary
  - Should work with Plan and Physician to identify substitutes
  - Right to a formulary exception
  - Procedures for requesting an exception
- CMS monitoring complaint rates
- See the 2007 Formulary and Transition Guidances
  - (http://www.cms.hhs.gov/PrescriptionDrugCovContra/03_RxContracting_FormularyGuidance.asp#TopOfPage)

Transition of the Duals

- **Why so many Issues?**
  - Switching over 6.4 million low income, high Rx users
    - OIG: 60% in plans that do not cover all their drugs
    - Because in lower cost plans, plans have fewer formulary drugs and have more use restrictions – more likely to switch
  - State files did not match CMS files and vice versa
  - Timely data to states on auto assignment
  - Some states re-enrolled duals into better plans.
  - Duals can switch plans once/month
  - CMS used SSA data to auto enroll LTC duals who might be in a home in a different state

2007: Pharmacy Quality Alliance

- Stakeholder led, similar to AQA
- PQA Mission statement:
  - *"to improve health care quality and patient safety through a collaborative process in which key stakeholders agree on a strategy for measuring performance at the pharmacy level; collecting data in the least burdensome way; and reporting meaningful information to consumers, plans, providers and other stakeholders to inform choices and improve health outcomes"*
- Pharmacy payment models for optimizing outcomes
- Two workgroups: Reporting and Metric Development
- Short term and long terms measures of pharmacy performance to help plans and beneficiaries assess quality of care provided by pharmacies.

2007: Co-branding

- Names and/or logos of providers (pharmacies/physicians) on plan ID cards may be confusing to beneficiaries
- Effective October 1, 2006, no co-branding name or logos of providers are allowed on member ID cards.
- Other marketing materials must include:
  - “Other <pharmacies/physicians/providers> are available in Our Network”

2007: Specialty Pharmacy

- Plans may not restrict access to certain drugs to "Specialty" pharmacies except:
  - When necessary to meet FDA limited distribution requirements
  - When extraordinary special handling, provider coordination or patient education is required… when such extraordinary requirements cannot be met by a network pharmacy

- Therefore, plans cannot limit solely due to placement in a "Specialty/high cost" tier

Retail vs. Mail Order Pharmacy

- Plans must allow enrollees to receive same benefits, such as 90 day supply of covered drugs, at network retail pharmacies if offered at mail order pharmacies.
- Plans were required to give pharmacies the chance to accept “mail rate” but plans MAY offer higher rate.
- Plans have to include in their networks a sufficient number of retail pharmacies that provide reasonable access to extended supplies at retail pharmacies.
- If pharmacies accept mail reimbursement rate,then benes pays the mail order cost sharing at retail
- If pharmacies accept a higher reimbursement rate, benes pay the mail order cost sharing PLUS difference between retail rate and mail rate.
- Differences in amounts paid by beneficiaries for retail prescriptions count toward TrOOP.

2007: Pharmacy Relationships

- Plans must comply with contracts
  - CMS is monitoring Pharmacist complaints
  - Pharmacies had “lower, slower” payments from Part D plans
- Plans must follow best practices for:
  - Consistent Coding
  - Secondary Messaging for:
    - Formulary rejections
    - Prior Authorization
    - Part B coverage
    - Other rejection edits
  - Plan Due Diligence for Part B versus D (see guidance)… want to stress the new procedures for B/D… more guidance coming

Pharmacist “Can” List

Providers Can:

- Provide names of plans with which they contract and/or participate
- Provide information and assistance in applying for LIS
- Provide objective information on specific Plan formularies, based on a patient’s medications and health care needs
- Provide objective information regarding Plans (e.g., benefits, cost sharing, utilization management tools)
- Distribute PDP materials, including enrollment forms
- Distribute MA and/MA-PD marketing materials, excluding enrollment forms

Pharmacist “Cannot” List

Providers Cannot:

- Direct, urge, or attempt to persuade, any prospective enrollee to enroll in a particular Plan or to insure with a particular company
- Collect enrollment applications
- Offer inducements to persuade beneficiaries to enroll in a particular plan or organization