MMA Section 641 Medicare Replacement Drug Demonstration
Qs & As
(Updated October 1, 2004)

1. **What drugs will be covered under the demonstration?**
   Answer:
   The list below shows the drugs and the conditions for which they will be covered under the demonstration.

DRUGS COVERED UNDER THE MEDICARE REPLACEMENT DRUG DEMONSTRATION*

Demonstration Covered Indication	**Drug/Biological—Compound Name (Brand Name)**
Rheumatoid Arthritis	Adalimumab (Humira)
	Anakinra (Kineret)
	Etanercept (Enbrel)
Multiple Sclerosis	Glatiramer acetate (Copaxone)
	Interferon beta –1a (Rebif, Avonex)
	Interferon beta –1b (Betaseron)
Osteoporosis (patient must be homebound)	Calcitonin – nasal (Miacalcin – nasal)
	Risedronate (Actonel)
Pulmonary Hypertension	Bosentan (Tracleer)
Secondary Hyperparathyroidism	Doxercalciferol (Hectoral)
Paget's Disease	Alendronate (Fosamax)
	Risedronate (Actonel)
Hepatitis C	Pegylated interferon alfa-2a (Pegasys) Pegylated interferon alfa-2b (PEG-Intron)
CMV Retinitis	Valcyte (Valganciclovir)
Acromegaly	Pegvisomant (Somavert)
Anti-Cancer	
Cutaneous T-cell Lymphoma	Bexarotene (Targretin)
Non-small cell lung cancer	Gefitinib (Iressa)
Epithelial ovarian cancer	Altretamine (Hexalen)
Chronic Myelogenous Leukemia	Imatinib Mesylate (Gleevec)
GI Stromal Tumor	Imatinib Mesylate (Gleevec)
Multiple Myeloma	Thalidomide (Thalomid)
Breast Cancer	Hormonal therapy

Demonstration Covered Indication	Drug/Biological—Compound Name (Brand Name)
Stage 2-4 only	Anastrozole (Arimidex)
	Exemestane (Aromasin)
	Letrozole (Femara)
	Tamoxifen (Nolvadex)
	Toremifene (Fareston)
Prophylactic agent to reduce ifosfamide-induced hemorrhagic cystitis	Mesna tablets (Mesnex tablets)

**This list has been updated as of 8/13/04.*

2. Why aren't these drugs covered for all conditions?

Answer:

The statute authorizing this demonstration required that the demonstration cover drugs that are replacements for drugs currently covered under Medicare Part B. In some situations, a physician may appropriately prescribe these drugs but they are not replacing any medication that is currently covered under Medicare Part B. Therefore, they do not meet the requirements for coverage under this demonstration.

3. How were these drugs selected?

Answer:

In order to determine what drugs would be covered under the demonstration, CMS established an inter-agency panel of clinicians to determine the criteria for defining what constitutes a "replacement" drug as provided in section 641 of the MMA. An initial set of criteria was shared with the public at an Open Door Forum held at CMS. Based on feedback received at this forum and subsequently in writing, the criteria were modified. To be covered under this demonstration, a drug/biological must meet all of the following criteria:

1. A drug or biological covered under this demonstration must meet the statutory requirement of being a replacement by eliminating the concurrent need for a currently covered drug or biological for a currently covered indication.

2. Coverage of the drug or biological in the demonstration is limited to FDA approved indications and, for any drug with an existing FDA approved indication, any additional indication if such additional indication is being reviewed by the FDA; and the requester has received documentation from the FDA that no filing issues remain.

3. The drug must be at least of equal efficacy to the covered drug for which it is a replacement.

4. Use of the drug represents an advantage in terms of access and/or convenience for patients compared to the currently covered drug.

5. Drugs are not eligible for coverage under this demonstration if the drug they are replacing is not commonly provided incident to a physician

service (for example, anti-hypertensives, antibiotics, oral hypoglycemics, etc.).

These criteria are consistent with the statutory requirement under section 641(a) of the MMA that the demonstration include only drugs and biologicals that are replacements for drugs currently covered under Part B.

4. When did the demonstration start?

Answer:

Applications were accepted starting July 6, 2004. The first group of beneficiaries was enrolled in August and started receiving coverage for their medications September 1, 2004. A second group of beneficiaries was enrolled at the end of September 2004 for coverage starting in October. Applications will continue to be accepted and eligible beneficiaries enrolled on a "rolling" basis until we reach our funding or enrollment limits.

5. How long will the demonstration last?

Answer:

The demonstration will run through 12/31/2005. In 2006, beneficiaries must enroll in the Medicare Part D drug benefit in order to continue to receive Medicare coverage for these drugs.

6. Who is eligible for the demonstration?

Answer:

In order to be eligible for participation in this demonstration, a beneficiary must meet the following criteria:

- The beneficiary must have Medicare Part A and Part B.
- Medicare must be the beneficiary's primary health insurance.
- The beneficiary must reside in one of the 50 states or the District of Columbia.

Beneficiaries who are members of Medicare Advantage or other Medicare coordinated care health plans as well as those covered under the traditional Medicare Fee-For-Service program are eligible to enroll.

Because a primary purpose of this demonstration is to increase access to important medications in advance of the full implementation of the Medicare Part D drug benefit in 2006, those beneficiaries who already have a comprehensive drug coverage (such as through TriCare, Medicaid, an employer or union sponsored plan, or a Medicaid Advantage plan) will not be eligible to enroll. However, beneficiaries without any drug coverage and beneficiaries with more limited drug coverage, such as that offered by Medicare supplemental ("Medigap") plans and some Medicare Advantage or other Medicare coordinated care health plans, are eligible to apply for participation. Beneficiaries with questions about eligibility may contact 1-866-563-5386 (TTY Number: 1-866-563-5387)

7. **Must beneficiaries be taking the replaced drug in order to be eligible for the demonstration?**

Answer:

Eligibility for this demonstration is not contingent upon whether a beneficiary is currently taking any specific drug, but only that the beneficiary has a condition for which their physician has prescribed or plans to prescribe (if the patient is selected to participate in the demonstration) a drug that is covered under the demonstration for that condition.

8. **How much will beneficiaries have to pay for drugs under the demonstration?**

Answer:

Cost sharing under this demonstration will be similar to what it will be under Medicare Part D in 2006. However, because of the shortened benefit year in 2004, out of pocket costs will be proportionately reduced from September through December 2004.

The table below shows what beneficiaries will have to pay out-of-pocket under this demonstration in 2004 and 2005. Any portion of the out-of-pocket costs paid by or which are reimbursed by a group health plan, insurer or otherwise, or similar third party payment arrangement will not count towards the true out of pocket ("catastrophic") limit.

BENEFICIARY COST SHARING UNDER THE STANDARD BENEFIT PACKAGE		
	2004 (Sept – Dec)	2005 (Jan- Dec)
Deductible Standard Benefit[1]	• $85	• $250
25% Coinsurance Range • Allowable Cost of Drugs • 25% Out of Pocket	 • $660 • $165	 • $2,000 • $500
100% Coinsurance "Donut" • 100 % Out-of-Pocket Payments (in addition to above)	• $950	• $2,850
True Out of Pocket ("Catastrophic") Limit[2]	• $1,695	• $5,100

[1] *Some low-income beneficiaries, those with incomes between 135% and 150% of the Federal Poverty Level, will have the deductible reduced to $20 in 2004. Other low-income beneficiaries will not pay any deductible in either year.*

[2] *To the extent that a group health plan, insurer, or other similar third party payment arrangement pays for or reimburses a beneficiary for any out-of-pocket costs, the catastrophic limit will be higher as those reimbursed costs cannot count towards the true out of pocket ("catastrophic") limit. Payments by certain charitable organizations or state pharmacy assistance programs may count towards a patient's total out-of-pocket costs.*

1. Total Allowable Cost of Drugs 2. Total Out of Pocket Payments After reaching this "catastrophic limit", the beneficiary pays…	• $1,200 The higher of: • 5% or • A fixed co-payment of $2 for generic or preferred multi-branded drugs or $5 for all other drugs	• $3,600 The higher of: • 5% or • A fixed co-payment of $2 for generic or preferred multi-branded drugs or $5 for all other drugs

9. Are there any subsidies for low-income beneficiaries?

Answer:

Yes. The same low-income benefit options that will be available under the Medicare Part D drug benefit in 2006 will be available immediately under this demonstration. This includes beneficiaries who are not full dual eligibles for Medicare and Medicaid but who receive assistance from their state Medicaid program in paying for their Part B premiums and/or Part B out-of-pocket expenses. Beneficiaries who believe they qualify for low-income assistance must complete and sign an attestation of income and resources. Enrollment in the demonstration will be determined on a "need-blind" basis without regard to whether a beneficiary has also submitted an application for the low-income subsidy. Cost sharing under all of the low-income benefit options is substantially reduced from the standard benefit.

10. Can a beneficiary use Medigap supplemental insurance to help pay for out-of-pocket costs under the demonstration?

Answer:

No. The same cost sharing rules that will be applied to the Medicare Part D benefit will also be applied under this demonstration. Under Part D, Medicare supplemental plans ("Medigap") will not be required, or permitted, to pay for beneficiaries' cost sharing under part D. Consequently, Medigap plans similarly may not pay or reimburse beneficiaries for out-of-pocket costs under the demonstration.

11. How will beneficiaries get their drugs under the demonstration?

Answer:

Caremark will administer the drug benefit under this demonstration. Once they are enrolled in the demonstration, beneficiaries will receive a demonstration-specific prescription drug coverage card. They may then fill their prescriptions through one of the many local neighborhood pharmacies that participate in Caremark's nationwide network or they may take advantage of mail order delivery to their home through Caremark's specialty pharmacy program. Approximately 98 percent of all local pharmacies participate in Caremark's network.

12. Where can beneficiaries get applications for the demonstration and where are they submitted?

Answer:

Applications may be downloaded from our web site: *http://www.cms.hhs.gov/researchers/demos/drugcoveragedemo.asp* or obtained by calling 1-866-563-5386 (TTY: 1-866-563-5387)any time after 8 a.m. Eastern time on July 6, 2004. Staff at the call center are available to help beneficiaries complete the application and/or to answer any questions they may have. Completed, signed applications should be sent to the following address:

Medicare Replacement Drug Demonstration
C/o TrailBlazer Health Enterprises, L.L.C.
P.O. Box 5136
Timonium, MD 21094

Applications received by 5 p.m. Eastern time on September 30, 2004 will be given preference. If more applications are received than either our enrollment or funding limits allow, then applicants will be chosen randomly among those who submit completed applications by this date. Beneficiaries who submit applications by August 16, 2004 will be eligible for an "early selection" that will enable them to have coverage by September 1, 2004.

13. Is there a limit to enrollment under the demonstration?

Answer:

Yes. The law authorizing this demonstration limited it to no more than 50,000 enrollees and $500 million in funding for drug costs.

14. How will applicants be chosen?

Answer:

Applications will be considered under two categories: (1) those seeking coverage for a covered cancer drug and (2) those seeking coverage for any other replacement drug covered under the demonstration. The purpose of creating two enrollment categories is to comply with the legislative intent that 40 percent of the available funding goes toward oral cancer treatments as specified in the Medicare Modernization Act of 2003 "Conference Agreement." As of October 1, applications will be reviewed on a "first-come" basis until we reach either our enrollment or funding limit. If an applicant is not selected due to space limitations, his or her name will be placed on a waiting list in case additional slots become available. For current information regarding whether new applications are being accepted, please call 1-866-563-5386; TTY: 1-866-563-5387.

15. How does this demonstration relate to the Medicare Discount Drug card?

Answer:

Beneficiaries who have a Medicare approved drug discount card may participate in the demonstration, but they may not use the Medicare approved drug discount card to

pay for drugs or biologicals covered under the demonstration. A separate demonstration-specific card will be issued to beneficiaries participating in this demonstration.

16. Can charitable organizations provide financial assistance to assist Medicare beneficiaries in paying for out-of-pocket costs under the demonstration?

Answer:

Under the demonstration, payments from bona fide charities and public programs or certain foundations may provide assistance to a beneficiary with cost sharing and still have that cost sharing count toward the out-of-pocket limit. These charitable organizations must meet specific qualifications including:

- The entity is an independent, non-profit, tax-exempt organization that is not subject to control, either directly or indirectly, by any donor;
- Eligibility for financial assistance is available for any financially qualified patient (suffering from the specific chronic illness targeted by the entity's programs) regardless of the particular physicians, providers, supplier of items or services, or drug that the patient may use;
- The entity makes its financial eligibility determinations using its own criteria and without regard to any contributions made by a donor whose products or services may be used by the patient;
- All patients have selected their providers of health care services prior to applying for financial assistance and remain free to change providers while receiving the entity's financial services; and
- The entity does not refer patients to any donor or other provider.

If the organization meets these requirements, then, as with state pharmacy assistance programs, the amounts paid will still count towards a beneficiary's out-of-pocket limit.

17. What other options do beneficiaries have for help in paying for their drugs if they are not eligible for or are not selected for this demonstration?

Answer:

Beneficiaries who are not able to take advantage of this demonstration can still save on their out-of-pocket costs for prescription drugs by purchasing a Medicare approved drug discount card. Lower income beneficiaries may also be eligible for a special $600 credit to help pay for their medications. Information on what cards are available and the cost of specific drugs is available by calling 1-800-MEDICARE or, for those with Internet access, at http://www.medicare.gov. In addition, beneficiaries may continue to receive all of the Medicare benefits they currently do, including any medications they currently receive in their doctor's office. Low-income beneficiaries should contact their State Pharmaceutical Assistance Program (SPAP).

In addition there are private foundations such as the Patient Advocate Foundation that are available to help Medicare beneficiaries and others with their medical care and pharmacy expenses. They can be reached by calling 1-800-532-5274 or, on the

web at http://www.patientadvocate.org/ . Depending upon the situation, this organization can assist a beneficiary in taking advantage of a drug company sponsored program and/or other programs that help patients pay for their medical care.

18. Are beneficiaries who currently receive their drugs through pharmaceutical company sponsored programs eligible to apply for this demonstration?

Answer:

Yes. Beneficiaries who are currently enrolled in or eligible for a drug assistance program sponsored by a manufacturer are allowed to apply to participate in this demonstration. Beneficiaries who are selected to participate in this demonstration may continue to receive assistance with their out-of-pocket expenses from these manufacturer-sponsored programs. However, if the drug assistance program does not qualify as a charitable organization under the rules of this demonstration (See response to question #16, above.), any payments by that organization to or on behalf of that beneficiary will not count towards the beneficiary's out-of-pocket limit. Staff at the call center set up by TrailBlazer to support this demonstration will be available to assist beneficiaries in comparing their current out-of-pocket expenses to what they would pay under the demonstration and whether or not they should consider submitting an application.

19. Can nurse practitioners sign the "Physician Certification Form"?

Answer:

Yes, if the nurse practitioner is writing the prescription for the demonstration covered drug.