



MEDICARE ACCESS FOR PATIENTS TO PRESCRIPTION DRUGS COALITION 2009 MAPRx PRIORITY ISSUES

Medicare Access for Patients to Prescription Drugs (MAPRx) coalition was formed in response to the passage of the Medicare Modernization Act (MMA). MAPRx is a growing coalition of 48 patient, family caregiver and health professional organizations, representing millions of Americans. We are committed to ensuring that Medicare beneficiaries have access to appropriate, affordable prescription drugs and safeguarding the well-being of patients with chronic diseases and disabilities under Medicare Prescription Drug Coverage (Part D). Our mission is to assure that beneficiaries have access to appropriate prescription drugs and accurate information as they make informed choices regarding their Medicare Part D coverage.

The following 2009 MAPRx Priorities are the result of a MAPRx member survey:

- Specialty Tier and Tiering
- Off Label
- Six Protected Classes
- Medication Substitution
- Comparative Effectiveness Research
- Two Year Wait Period
- Step Therapy/Dose Restrictions

Position Statements on the 2009 MAPRx Priority Issues:

More than 38% of all Medicare beneficiaries live with three or more chronic conditions and 29% have cognitive or mental impairments according to the Kaiser report: *“Medicare a Primer, 2009”*. Generally speaking, the Medicare Part D program has been a success but for the millions of Medicare beneficiaries with chronic illnesses and/or disabilities, access to affordable medication is increasingly more difficult, more expensive and less transparent than for typical Part D beneficiaries.

Specialty Tier and Other Tiering Issues:

In 2007, specialty tier medications were used by 4.4% (over 2 million) beneficiaries with expenditures that accounted for about 10% of the cost of all drugs under Part D. Drugs in a plan’s formulary are organized in different drug tiers with the most expensive drugs put into higher and specialty tiers. Our concern is that increasingly, more drugs have been added into specialty tiers, costing beneficiaries significantly more every year and limiting access. Individuals with chronic illnesses are often prescribed expensive medications and are paying a percentage of the cost of the drug, rather than a flat co-pay. Medicare patients are often noncompliant with treatment plans or biologic medications because of excessive co-insurance of 25 percent or greater. It is not uncommon for an individual with cancer, multiple sclerosis, arthritis or other chronic conditions, taking several medications, to pay several thousands of dollars per month out of pocket until they reach catastrophic coverage. Additionally, plans have designed their tiering system to switch between copayments and coinsurance leading to

significant confusion among beneficiaries, especially those on multiple and/or expensive medications who try to compare plans. Most beneficiaries are unaware that they can request an “exception” in order to have the drug moved to a lower, less expensive tier. However, no exceptions are allowed for Specialty Tiers, and this raises concerns about access as the specialty tiers grow in the Medicare Part D program.

CONGRESSIONAL ACTION NEEDED

- Implement a cap on total cost-sharing for beneficiaries.
- Ensure that beneficiaries be allowed to appeal cost sharing for specialty tier drugs.
- Ensure that plans are not permitted to switch their formularies or tier (cost of drug) after the marketing period and to adhere to the strict guidelines already in place.
- Ensure that the CMS web-based tool, used by beneficiaries to compare plans, is improved to provide accurate, comparable information.

Off Label:

Medicare regulations exclude payment for drugs under Part D that are prescribed for a use other than those approved by the Food and Drug Administration (FDA) or for a use that is not cited in specific medical compendia. Exclusive reliance on FDA indications and a limited number of compendia may prevent access to medically necessary, life-sustaining prescription medications. Current standards for coverage of drugs, used off-label, under Part D are inconsistent with generally accepted medical guidelines including Medicare Part B regulations, many Medicaid programs, and private insurance rules, which allow for consideration of evidence of effectiveness in peer-reviewed literature. Medicare prescription drug plans should provide access to ALL medically accepted uses for drugs – including those uses that are cited in peer review literature. In fact, many medically necessary and safe off-label uses of drugs could prevent the need for more acute and costly care such as hospitalizations. Moreover, allowing greater access to safe and effective drugs used off-label preserves the doctor-patient relationship. Physicians are experts and in the best position, in consultation with their patients, to determine the most suitable treatment. Creating a policy that allows for a case by case appeal and analysis of the appropriateness of an off-label use of a drug under Part D will help improve the quality of life for a population in desperate need of greater treatment options.

CONGRESSIONAL ACTION NEEDED

- Ensure that Medicare prescription drug plans provide access to ALL medically accepted uses for prescription drugs prescribed by the beneficiary’s physician.
- Change current Medicare Part D legislation to be consistent with that of Medicare Part B.
- Establish, in health reform legislation, a process by which a Part D beneficiary can appeal a plan’s decision to deny coverage of a prescribed off label drug or biologic. Legislation is needed to grant coverage, on a case by case basis, based on supportive clinical evidence cited in peer reviewed medical literature.

Six Protected Classes:

Currently there is guidance from Center for Medicare and Medicaid Services (CMS) that directs plans to cover all, or substantially all, of the drugs in the six protected classes (anti-neoplastics,

immune-suppressants, anti-retrovirals, anti-convulsants, anti-depressants and anti-psychotics).

MAPRx members supported the *Medicare*

Improvements for Patients and Providers Act of 2008 (H.R.6331) that was intended to strengthen the current CMS guidelines regarding plan coverage of the six protected classes.

CONGRESSIONAL ACTION NEEDED

- Ensure that Medicare Part D plans continue to cover all, or substantially all drugs in the Six Protected classes, as intended by Congress in the MIPPA provisions.
- Ensure that quantity and dosage limits do not apply to medications in the six protected classes.
- Combat the abusive use of utilization management techniques such as step therapy, therapeutic substitution and prior authorization regarding the drugs in these classes.

Medication Substitution:

MAPRx members are generally not opposed to use of generic drugs and realize that about two thirds of all prescriptions are filled with generics. However, we are very concerned about the practice of medication substitutions, whereby Medicare plans can mandate that a beneficiary be prescribed a different (usually less expensive) drug within the same class of drugs or a different formulation of a drug (brand to generic or generic to generic). Substitution, for any reason, can cause problems for patients and should not be mandated by anyone other than the medical provider and a patient's informed consent. In addition, there should be mechanisms in place to provide access and coverage to a specific, physician prescribed therapy when the physician has directed its need for a patient. For example: a person with epilepsy, who has maintained seizure control for many years, could be required to change to a different anti-convulsant with a different chemical makeup. This switch, which could occur between brand and generic or generic versions of the same drug, could mean a breakthrough seizure with unintended and dire health and life consequences. For the cost savings and quality of life issues, Medicare Part D plans should implement a process where physician's can ensure that their patients receive needed therapies. Another area where substitution and switching is a concern is with biologics. Biologics are made from living cells and are therefore more complex to replicate. Because of the unique characteristics of biologics, the decision about which product to prescribe is best made between the physician and the patient. To minimize potential adverse health outcomes, automatic substitution without the consent of the treatment physician should not be permitted. Therapeutic substitution of biologics is unacceptable, could lead to adverse reactions, unnecessary illness, hospitalizations, and is contrary to the original intent of Medicare law that vows not to stand in the way of physician-directed care.

CONGRESSIONAL ACTION NEEDED

- Ensure that automatic substitution of any prescribed drug, for any reason, without the knowledge and consent of the treatment physician is not permitted.

Comparative Effectiveness Research:

Comparative effectiveness research results must not be used to drive coverage or reimbursement of treatment nor interfere with a physician and their patient to make health care decisions. Evaluation of treatments, used to guide the medical community, must be tested in real healthcare settings to determine their impact on individuals and various unique subpopulation such as those which chronic illness and disability. New delivery models that are founded on principles of evidence-informed medicine, empowered by electronic records, respectful of a patient's unique situation and committed to reducing out of pocket costs while reimbursing for care coordination are proving to be the most cost-effective health reform strategies. Although MAPRx members encourage funding for efficacy studies of various medical treatments, we are concerned that payers will make decisions to cover or deny a treatment, drug or therapy, prescribed by licensed practitioners, based solely on comparative effectiveness research. Although widely viewed as a tool to create a healthcare system that is more consistent, safe, effective, efficient and affordable, comparative effectiveness should never be used as a tool to deny coverage for drugs or treatments.

CONGRESSIONAL ACTION NEEDED

- Ensure that the medical decision making process that occurs between healthcare providers and their patient is safeguarded.

Two Year Wait Period:

Nearly 7 million Americans under age 65 qualify for Medicare due to severe and permanent disabilities. However, their Medicare coverage does not begin immediately or automatically when they are deemed disabled. The law states that they must wait two full years from the date their Social Security Disability Insurance begins before they can receive Medicare. This two year waiting period exposes millions of Americans to financial hardship, pain and suffering. According to a 2003 study by the Commonwealth Fund as many as one-third of those in the waiting period may be uninsured or have inadequate insurance coverage. By the time they obtain Medicare coverage, 77 percent are poor or nearly poor. Congress has already acknowledged that the 24-month waiting period can be a death sentence for people with specific diseases—it has eliminated the waiting period for people with amyotrophic lateral sclerosis (Lou Gehrig's disease) and for end-stage renal disease (ESRD) for which a lack of treatment is fatal.

CONGRESSIONAL ACTION NEEDED

- Congress must continue their work to totally eliminate the two year waiting period for *all* people with disabilities.

Step Therapy:

Many plans are expanding their use of utilization management tools with step therapy being imposed most frequently. Plans require that beneficiaries must first try a drug or biologic (self-injected versus infused) that has not been prescribed for them and be exposed to the risk of suffering an adverse reaction or otherwise demonstrate that it is therapeutically ineffective before they will cover the medication(s) originally prescribed by their physician. This utilization

management technique is contrary to the intent of Medicare legislation passed over 40 years ago that states: “Nothing in this title shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided...” An insurer is permitted to over ride the health care provider’s practice of medicine by forcing the utilization of medications or therapies that may be inappropriate. Additionally, there is a lack of information and transparency. Many beneficiaries are not aware of their plans’ new utilization management tools, the importance of calling their plan to inquire about upcoming changes, or their right to appeal and obtain access to needed physician prescribed treatments.

CONGRESSIONAL ACTION NEEDED

- Ensure implementation and full compliance with a CMS memorandum which indicates that beneficiaries should receive an explanation of how utilization management (UM) tools will impact them before signing up for a plan.
- Request statistics from CMS on how many plans are non-compliant with providing beneficiaries an explanation of the impact of a plan’s UM techniques.
- Request a study on how step therapy and all other utilization management techniques impact beneficiaries.

Dose Restriction or Quantity Limits:

Plans currently have the right to limit the number of doses a beneficiary is allowed to obtain or limit the quantity of drugs that are covered over a certain period of time, regardless of the physician’s prescription. The appeal process is often time consuming and puts an undue burden on the physician to continually justify the need for their patients’ medications, the quantity or amount necessary for effective medical treatment.

CONGRESSIONAL ACTION NEEDED

- Ensure that plans are not permitted to impose artificial dose restrictions or quantity limits on Part D beneficiaries.

Please contact Maureen Mitchell, Convener MAPRx if you have any questions regarding this document: Mitchell@lupus.org, (office) 202-349- 1170, (cell) 202-494-8383.

Sincerely,

- Alzheimer’s Association
- American Autoimmune Related Diseases Association
- American Society for Consultant Pharmacists
- Arthritis Foundation
- Easter Seals
- Epilepsy Foundation
- Lupus Foundation of America
- Men’s Health Network
- Mental Health America
- National Alliance on Mental Illness
- National Council for Community Behavioral Healthcare
- National Grange
- National Health Council
- National Kidney Foundation
- National Organization for Rare Disorders
- RetireSafe

- The Arc of the United States
- United Cerebral Palsy
- United Spinal Association