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March 14, 2012

The Honorable Joseph J. Crisco and Robert W. Megna, Co-Chairs, and Members
Insurance and Real Estate Committee
Room 2800, Legislative Office Building
Hartford, CT 06106

RAISED BILL 5486 An Act Concerning Health Insurance Coverage for Prescription Drugs and Breast Thermography

Senators Crisco, Representative Megna and Members of the Insurance and Real Estate Committee:

The Arthritis Foundation is concerned about the barrier that excessive cost sharing in commercial health insurance policies creates for access to newer biologic therapies that have proven to reduce disability. High out-of-pocket costs can result from high co-pays, co-insurance or the use of specialty tiers for biologics used to treat rheumatoid and other inflammatory types of arthritis.

For people with inflammatory forms of arthritis, newer biologic therapies have in repeated studies shown that they prevent joint destruction and related disability¹. Since they are produced within living cells, rather than from synthetic chemicals in the laboratory, the cost of biologics are high and no generics are available. Annual costs for biologics used to treat inflammatory arthritis can exceed \$20,000 per patient².

What has happened over the past several years is that instead of the traditional three-tier drug formulary (Tier 1=generics, Tier 2=preferred brand name drug; Tier 3-non-preferred brand name drug), plans have begun to add a fourth and even a fifth "specialty" tier, which usually have a co-insurance or cost-sharing percentage rather than a fixed co-pay. These cost-sharing percentages can range from 25-50% of the cost of the specialty medication.

Goldman and colleagues completed a study that analyzed the change in members' utilization given a change in their cost-sharing for specialty drugs, including rheumatoid arthritis. The study included pharmacy and medical claims from 55 health plans offered by 15 large employers with 1.5 million beneficiaries in 2003 and 2004. The study showed that doubling the co-pay (which is a fixed amount much less than co-insurance) resulted in a 21% reduction in use among people with rheumatoid arthritis³. An earlier study by the same authors concluded that high cost sharing delays the initiation of drug therapy for patients newly diagnosed with chronic disease⁴. In rheumatoid arthritis, studies show that most of the joint damage occurs in the first three years of disease, so any delay increases the risk for lifelong disability.

We realize that insurers are using excessive cost-sharing approaches and specialty tiers to control costs for these very expensive drugs. Insurers have other cost control mechanisms, such as prior authorization, that can be used to insure that very expensive medications are prescribed appropriately for patients. Creating or maintaining cost barriers to effective treatments may well drive total costs higher by perpetuating poor outcomes.

The current version of this bill seeks to restrict cost sharing by limiting annual out-of-pocket expenses for prescription drugs (except for high deductible plans) to no more than \$1,000 per individuals and \$2,000 per family. The problem that we have seen in similar legislation from other states is that setting a dollar amount limit does not allow for inflation and would need to be legislatively changed as the cost of the medications increased. There are also potential problems with the bill's definition of specialty drugs, defined by Medicare as those costing \$500 or more, and with the lack of a definition for chronic conditions.

The Arthritis Foundation supports legislation to cap out-of-pocket costs for specialty medications. For your information, attached is an editorial by our national CEO, John Klippel, MD from the January/February *American Journal of Pharmacy Benefits* on this issue.

Thank you for your consideration.

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Excessive Cost Sharing as a Barrier to Health for People With Arthritis

John H. Klippel, MD

B iologic therapies are game changers. Rheumatologists like me, who were in practice before the first biologic drug was approved for rheumatoid arthritis (RA) in 1998, remember far too well patients who failed to improve with so-called disease-modifying medications. These non-responders can, to this day, tally their many medication trials and failures, hospitalizations, and joint surgeries and joint replacements. They can tell you how their lives were forever changed by the loss of dreams, relationships, careers, and jobs they struggled to keep but couldn't. They can tell you about their difficulties with activities of daily living, coping with chronic pain, and so much more. And I'll never forget the people who died far too young because of the damage caused by their RA.

With the advent of biologic drugs, difficult-to-treat cases have become possible-to-treat. When a new class of medications brings significantly improved outcomes, and reduces the likelihood of future pain, surgeries, wheelchairs, and early death, it's a game changer.

Unfortunately, too many rheumatologists and their patients are forced to live in the past. When a patient presents with active joint disease and poor prognostic indicators and fails to respond to or cannot tolerate adverse effects of the traditional disease-modifying antirheumatic drugs, like methotrexate or sulfasalazine, biologics are a logical and valid next step. But it's an impossible step for too many of those patients who have tiered high-copayment or coinsurance prescription plans.

The Problem With Specialty Tiers

Biologic medicines are arguably the most significant treatment advancement of this era, but because they are produced within living cells, rather than from synthetic chemicals in the laboratory, the costs of biologics are high. Annual costs for these medications can exceed \$20,000 per patient.¹ In commercial private plans, cost sharing of these drugs, for which there are no generic versions, varies from 20% to 50% of the treatment costs. In the Medicare Part D program, cost sharing can vary from 25% to 33% of the actual cost of the medication. As

a result, patients' out-of-pocket expenses can run from several hundred to thousands of dollars a month for that single medication.

The Henry J. Kaiser Family Foundation reported in 2009 that 87% of stand-alone Medicare Part D prescription drug plans and 98% of Medicare Advantage prescription drug plans had specialty tiers. Under Medicare guidelines, specialty tiers are restricted to drugs which cost more than \$600 per month.²

In the private commercial sector, another 2009 study published by the Kaiser Family Foundation showed that more than three-fourths of workers with prescription-drug coverage were in plans with 3 or more tiers of drug coverage. In 2000, only 27% of workers with prescription-drug coverage had a plan with 4-tier coverage.³

Tiered formularies and the resulting excessive cost sharing is more than a financial issue. It leads to nonadherence, delays in treatment, and poor outcomes.⁴ Even those who respond well to biologic drug therapy may stop taking it or skip doses because they simply cannot afford it. In fact, the *Journal for Managed Care Pharmacy* reported that a monthly copay greater than \$100 for a biologic drug that blocks tumor necrosis factor, or TNF, was associated with increased rates of prescription abandonment. People who carefully choose an insurance plan based on its formulary and cost-sharing structure may be out of luck, at least for the plan year, if the insurer moves their drug into a specialty tier, requiring an impossibly high copayment every month.

Concerns over out-of-pocket expenses also delay the initiation of drug therapy for newly diagnosed patients.⁴ The Arthritis Foundation advocates early diagnosis and aggressive treatment of RA to preserve joint structure. In RA, studies show that most joint damage occurs in the first 3 years of the disease. Any delay increases the risk for lifelong disability.

In Search of Solutions

Excessive cost sharing is a problem that goes beyond the individual. Arthritis, overall, is the nation's leading cause of disability, and it costs the US economy \$128

billion annually, including \$81 billion in direct costs (eg, medical expenditures) and \$47 billion in indirect costs (eg, lost earnings). Maintaining barriers to effective treatment may well drive those costs higher by perpetuating poor outcomes.

The 2010 Patient Protection and Affordable Care Act will not resolve the issue. While this act will bring much-needed reform to healthcare, it will not regulate prescription drug costs for those with commercial insurance. A year ago, it at least provided some relief to seniors on Medicare by reducing drug costs 50% when they are "in the donut hole," the gap during which they must pay the full cost of their medications. Still, few regulations exist that avert trends toward increased cost sharing, coinsurance, and specialty tiers.

Some states are taking action. In 2010, New York passed legislation prohibiting the use of specialty tiers. Other states including Maryland, California, Delaware, and Vermont are considering legislation on specialty tiers.

The Arthritis Foundation supports these actions and several federal legislative efforts, including changing Medicare Part D and its policies regarding specialty tiers; revising the Affordable Care Act to incorporate changes

that cap out-of-pocket costs for specialty medications; and supporting legislation that makes manufacturers' patient assistance programs available to Medicare beneficiaries.

Together, we must ensure that all patients with arthritis or other chronic diseases have affordable access to biologic therapies. Access for all is the only way we can eliminate discrimination and help provide the best possible healthcare for everyone, regardless of income or insurance plan.

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