Arthritis Foundation Position Statement on Biosimilar Substitution

ISSUE

The Affordable Care Act creates a regulatory pathway for the approval of a new generation of biologic medications called “biosimilars”. Biosimilar medications have the potential to provide safe and effective treatment to people with arthritis at a potentially lower cost than the name-brand biologic medications.

BACKGROUND

Biologic medical products have offered significant therapeutic benefit to thousands of patients with arthritis and have also helped many others living with complex chronic diseases. This new class of biosimilars is expected to enter the market place in the near term. These complex genetically engineered products offer new treatment opportunities for people with forms of inflammatory autoimmune arthritis and other chronic diseases. Through special review processes conducted by the FDA some of these biosimilar products may be deemed to be therapeutically equivalent or interchangeable with an original biologic or reference product. In the future, interchangeable biosimilars recognized by the FDA may be substituted for an approved biologic. However, as both biologics and biosimilars are complex treatments requiring careful therapeutic monitoring, pathways for substitution require communication and transparency in all pharmacy transactions.

ARTHRITIS FOUNDATION POSITION

The Arthritis Foundation supports legislation that provides a pathway for biosimilar substitution and should provide the following:

- Communication to the patient upon substitution.
- Communication to the prescriber within 48 hours of the substitution.
- Retention of substitution records for a minimum of 5 years.
- Permit a physician override to substitution where patients are stable on a prescribed biologic.
- Biosimilar medications must be approved by the FDA as therapeutically equivalent and interchangeable to the original biologic.
- Biosimilar medications must have an individualized and unique name noticeably different than the reference biologic.

October, 2014
Arthritis Foundation Position Statement on Health Insurance Plan Formulary Transparency

ISSUE

Most health insurance plans have a website which allows consumers to shop for health care coverage and compare health plan costs and benefits. Generally, these websites do not include specific information on cost sharing, prior authorization or step therapy requirements as they relate to specific medications.

BACKGROUND

Transparency in insurance health plans can be used to help people with arthritis when they are comparing the provisions and benefits of insurance plans. Formulary transparency enables consumers to have information on specific drug coverage, out of pocket expenditure obligations, limitations on coverage, prior authorization requirements and step-therapy protocols.

People with substantial prescription drug needs, especially those living with chronic conditions such as rheumatoid arthritis, need to be able to access information and make comparisons of health insurance plans. Formulary transparency makes it easier for people with serious conditions to insure the health insurance plan they choose covers the prescription drugs and therapies they need.

ARTHRICITIS FOUNDATION POSITION

The Arthritis Foundation supports legislation that provides formulary transparency in health insurance plans and should require the following:

- Maintain a clear searchable listing of medications covered in a plan’s formulary by drug name and disease type.
- Disclose all co-payment and co-insurance obligations for each medication.
- Disclose special requirements for each medication including step therapy and prior authorization.
- Disclose formulary changes on a monthly basis and within 72 hours during open enrollment.
- Provide alternative methods for formulary listings to those people without internet access.

October 2014
Arthritis Foundation Position Statement on Narrow Provider Networks/Network Adequacy

ISSUE

Many people with arthritis who are enrolling in health insurance plans are learning that the availability of doctors, specialists and hospitals through those plans is extremely limited. Patients who do not have access to necessary medical care through their insurance plans are forced to use “out-of-network” providers for care. Because insurers do not pay for out-of-network care, patients only have access to care that is specific to their needs by absorbing a substantial cost sharing obligation or by switching doctors.

BACKGROUND

Many health insurance plans limit the number of doctors, hospitals, facilities and services that are available to their plan enrollees. Those providers that are in the plan’s network are generally covered and the use of a provider that is not within the plan is considered out-of-network and is not covered by the plan. Patients who use out-of-network providers typically pay significantly more than they would for providers in a plan – or even all of the cost without any contribution from their insurer.

A plan with few choices is considered to have a “narrow network”. Some narrow networks have been identified without the availability of a nearby hospital, absence of specialists, facilities in geographically unfavorable distances from population centers and physicians who are over-booked or not taking on new patients. The inadequacy of a narrow network to serve the diverse needs of its enrollee population can serve as a direct impediment for access to care.

The Affordable Care Act (ACA) requires all insurers providing qualified health plans through a health insurance exchange to achieve certain network adequacy requirements (45 CFR 155.1050/156.230). The ACA mandates the minimum requirements and permits the states to develop even more rigorous requirements for exchange plans. Under the ACA, insurers must:

1. Have a network for each plan with a sufficient number, geographic distribution, and types of providers...to ensure all services are accessible without unreasonable delay; and

2. Include in networks a sufficient number and geographic distribution of essential community providers to ensure reasonable and timely access to a broad range of such providers for low-income and the medically underserved.

The network adequacy requirements of the ACA are limited only to insurance acquired through the health insurance exchanges and do not apply to commercial insurance policies. Because current state laws do not specifically provide against narrow or inadequate networks, state legislation is being considered to solve the problem. While corrective legislation is pending, some state insurance commissioners have taken it upon themselves to impose adequate network requirements as a condition of offering plans in their respective state.
ARTHRITIS FOUNDATION POSITION

The Arthritis Foundation supports legislation or regulation that restricts narrow or inadequate provider networks and should provide the following:

- Insurance plans must ensure access to care in a way that does not negatively impact an enrollee’s health.
- Insurance plans must ensure a minimum level of access to care based on clinical appropriateness, the nature of the specialty and the urgency of care.
- Insurance plans must ensure a sufficient number of geographically accessible health care providers for the number of enrollees in a given region.
- Insurance plans must ensure a network that includes sufficient health care providers in each area of specialty practice to meet the needs of the enrollee population.
- An insurance plan that is unable to provide sufficient access to required providers must ensure that an enrollee may obtain a covered benefit at no greater cost to the person than if the benefit were obtained from participating providers.
- Insurance plans must ensure the ability to select specialty practice health care providers within a reasonable travel time and distance - taking into account the conditions for provider access in rural areas.
- Insurance plans must ensure a sufficient range of services.
- Insurance plans must not exclude any type of health care provider as a class.

October 30, 2014
Arthritis Foundation Position Statement on Prior Authorization

ISSUE

Prior authorization is a process often utilized by insurance companies as a requirement before specialty drugs are dispensed. This review period creates delays in the dispensing of the medication and the patient’s access to necessary care. Each insurance plan has its own set of forms and approval procedures which may vary for different medications or therapies. This is often a cumbersome process that causes significant delays in medication accessibility for patients.

BACKGROUND

Health insurance plans require physicians to fill out a prior authorization form when the provider prescribes a specialty medicine or treatment for a drug that is not covered under the insurer's formulary. The current prior authorization system creates an unnecessary burden on patients, pharmacies and doctors, as each insurer has its own unique systems, requirements and approval protocols.

This approach to prior authorization means that many hours per week are needed by physicians and pharmacists just to complete and process these forms. Additionally, physicians and patients often are forced to wait days to receive notification of an approval or denial of prescriptions and must repeatedly follow up with insurers to confirm that all the necessary paperwork has been submitted.

ARTHRITIS FOUNDATION POSITION

The Arthritis Foundation supports legislation that would standardize the use of prior authorization protocols and provide the following:

- Establish a single standardized form (paper or electronic) for providers to submit prior authorization requests for medications and therapies.
- Require prior authorization requests to be completed within 48 hours of submission or be deemed automatically approved.

October, 2014
Arthritis Foundation Position Statement on Out of Pocket Medication Costs

ISSUE

Health insurers have historically charged fixed co-pays for different tiers of medications. As an example the co-pays might be set at $10/$20/$50 for the three tiers. Some health insurance policies are now moving vital medications (mostly biologics) into a fourth specialty tier. Specialty tiers require people with arthritis and other conditions to pay a percentage of their drug cost—often 25% to 50%—rather than a fixed dollar amount co-payment.

BACKGROUND

High cost sharing, also known as co-insurance, is a barrier to medication access for patients with chronic, disabling, and life threatening conditions and may result in serious harm. Cost-sharing for prescription medications should not be so burdensome that it restricts or interferes with access to necessary medications, which can lead to negative health outcomes and additional costs to the healthcare system.

Since many people with arthritis also suffer with chronic diseases such as diabetes or heart disease, their monthly medication expenditures to lead productive lives can include several kinds of medications. Ensuring that people with arthritis have access to affordable quality treatments and medications is a guiding principle of the Arthritis Foundation.

ARTHРИTIS FOUNDATION POSITION

The Arthritis Foundation supports legislation that limits out of pocket costs and should provide the following:

- Limits the cost of a 30 day supply of any single prescription medication to no more than $150 a month.
- Limits the total aggregate monthly out of pocket cost for all prescription medications.
- Limits the total annual out of pocket expenditures for all prescription medications at a maximum of 50% of the ACA total out of pocket limits for an individual or family plan.

October 2014
Arthritis Foundation Position Statement on Step Therapy/Fail First

ISSUE

An increasing number of insurers are utilizing step therapy or fail first policies that require patients to try and fail one or more formulary covered medications before providing coverage for the originally prescribed non-formulary or non-preferred medication.

BACKGROUND

Step therapy or “fail first” is the practice by insurers of requiring patients to test use of a safe lower cost drug or service before permitting more expensive drugs or services. Step therapy is an established benefit management tool that is used by commercial carriers, self-insured employers, Medicare Advantage/Part D programs, and Medicaid.

When a patient changes insurers or a drug they are currently taking is moved to a non-preferred status patients may be put through the step therapy process again. Some step therapy protocols impose these requirements on stable patients.

ARTHРИTIС FOUNDATION POSITION

The Arthritis Foundation supports legislation that provides limitations on step therapy/fair first protocols and believes the following provisions are essential to protect patients:

- Permit a prescriber to override the step therapy when patients are stable on a prescribed medication.
- Permit a physician to override the step therapy if the physician expects the treatment to be ineffective based on the known relevant physical characteristics of the patient and the known characteristics of the drug regimen; will cause or will likely cause an adverse reaction by or physical harm to the patient; or is not in the best interest of the patient, based on medical necessity.
- Require health insurance plans to incorporate step therapy approval and override processes in their preauthorization applications.
- Prohibit insurers from requiring insured patients from having to fail a prescription medication more than once.
- Limit any single step therapy protocol to a maximum of 60 days.
- In circumstances where an insured is changing health insurance plans, the new plan may not require the patient to repeat step therapy when that person is already being treated for a medical condition by a prescription drug provided that the drug is appropriately prescribed and is considered safe and effective for the patient’s condition.
- When a health insurance plan changes formulary design, the plan cannot limit or exclude coverage for a drug for an insured if the drug previously had been approved for coverage by the plan for a medical condition of the person and the plan’s prescribing provider continues to prescribe the drug for the medical condition.

October, 2014