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June 17, 2015

BY ELECTRONIC DELIVERY

Senator Orrin Hatch
Chairman, Senate Committee on Finance
104 Hart Senate Office Building
Washington, D.C. 20510

Senator Johnny Isakson
Senate Committee on Finance
131 Russell Senate Office Building
Washington, D.C. 20510

Senator Ron Wyden
Ranking Member, Senate Committee on Finance
221 Dirksen Senate Office Building
Washington, D.C. 20510

Senator Mark Warner
Senate Committee on Finance
475 Russell Senate Office Building
Washington, D.C. 20510

Dear Chairman Hatch, Ranking Member Wyden, Senator Isakson, and Senator Warner:

On behalf of AbbVie, I write to commend you on the creation of a chronic care working group aimed at improving care for Medicare beneficiaries with chronic conditions. We agree the impact of chronic disease can be staggering. As noted by the Centers for Disease Control, approximately 117 million adults in the United States (U.S.) had one or more chronic conditions, and of the top ten causes of death in 2010, seven were chronic diseases.[1] Furthermore, 21.4 million Medicare beneficiaries suffer from at least two or more chronic conditions.[2]

AbbVie is a global, research-based biopharmaceutical company focused on developing medicines to address today's most difficult health issues – from life-threatening illnesses to chronic diseases. Our more than 30 products benefit the lives of patients in over 170 countries, treating rheumatoid arthritis, psoriasis, Crohn's disease, HIV, hepatitis C, cystic fibrosis complications, thyroid disease, advanced Parkinson's disease, ulcerative colitis, and complications associated with chronic kidney disease.

In the United States, AbbVie employs over 12,000 people, including scientists, researchers, manufacturing specialists, and regulatory experts. Globally, there are approximately 28,000 AbbVie employees in 15 research and manufacturing facilities.

AbbVie is deeply invested in helping improve the care of beneficiaries with chronic conditions and is closely following potential policy solutions, including the prevention or limitation of non-medical switching of prescription medications, and care coordination for oncology patients. AbbVie sincerely appreciates the opportunity to offer the following responses to item #4 "the effective use, coordination, and cost of prescription drugs" of the Committee on Finance's request for comments.

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[1] Centers for Disease Control and Prevention (CDC). *Chronic Diseases: The leading causes of death and disability in the United States.* http://www.cdc.gov/chronicdisease/overview Last accessed June 2015.

[2] Centers for Medicare & Medicaid Services (CMS). *Chronic Conditions Among Medicare Beneficiaries; Chartbook: 2012 Edition*, p. 6, available at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/2012Chartbook.pdf. 2012.

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Background on Non-medical Switching

When stable patients are switched from one therapy to another, there can be significant implications to patients and the health care system. Switching medications for non-medical reasons can lead to unintended effects, such as increased utilization of health care services (hospitalization, additional physician visits, additional lab tests, emergency room visits) and other associated costs.[3][4] For example, when patients with rheumatoid arthritis stabilized on adalimumab, a biologic drug, were switched to another product, they incurred 42% more emergency department visits and 12% more outpatient visits for any conditions than those left on adalimumab.[5]

In Medicare Part D, the Centers for Medicare & Medicaid Services (CMS) currently prohibits health plans from "implement[ing] prior authorization or step therapy requirements that are intended to steer beneficiaries to preferred alternatives" for patients stable on therapies included in the six protected classes. CMS applies this policy to beneficiaries already enrolled in a Part D plan as well as to new enrollees who were actively taking a therapy prior to enrollment in a plan.[6]

However, CMS permits health plans to switch a patient who is stable on a biologic to another biologic without the consent of the physician or patient. Similarly, when biosimilar products are available on the market, under current Part D rules, plans could switch patients who are stable on a biologic to a biosimilar product without physician or patient consent.

Of note, biologic medicines, including biosimilars, are made by or derived from living organisms or cells. They have complex and very large structures and are also known as large molecules. Conventional medicines, such as acetaminophen, are based on relatively simple chemical molecules. These medicines are sometimes known as small-molecule medicines and they are made by combining specific chemical ingredients using a relatively less complicated manufacturing process. Biosimilars are biologics developed to be similar to an already licensed biologic. They are similar to the originator biologic, but not the same. Biosimilars are not generic originator biologic medicines because it is impossible to produce an exact copy of a biologic medicine. Each biologic is unique because the manufacturing processes and host cell lines that are proprietary and unique to a particular company cannot be duplicated.

Patients who are stable on a therapy should be able to remain on that therapy, as long as they and their provider feel it is necessary. This is important because individual patients are likely to respond differently to different therapies—even those within the same class—which can significantly impact their adherence to a therapy (e.g., if one therapy causes negative side-effects), and, in turn, their health outcomes. Furthermore, biosimilars present new complexities and potential safety concerns not envisioned by CMS when it implemented the current Part D requirements.

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[3] Rendas-Baum R, Wallenstein GV, Koncz T, et al. Evaluating the efficacy of sequential biologic therapies for rheumatoid arthritis patients with an inadequate response to tumor necrosis factor-inhibitors. Arthritis Res Ther. 2011; 13(1):R25.

[4] Signorovitch J, Bao Y, Samuelson T, Mulani PM. Abstract presented at: EULAR 2012, Berlin, Germany. Ann Rheum Dis. 2012;71(suppl3):717.

[5] Signorovitch J, Bao Y, Samuelson T, Mulani PM. Abstract presented at: EULAR 2012, Berlin, Germany. Ann Rheum Dis. 2012;71(suppl3):717.

[6] Centers for Medicare & Medicaid Services (CMS).Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, Rev. 10, February 2010. http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter6.pdf

Proposed Solution

AbbVie encourages the work group to extend patient protections currently in place for the six protected classes—to allow patients who are already stable on a therapy to remain on that therapy both within a plan year and when switching plans—beyond just the six protected classes to all Part D beneficiaries stable on a therapy. For example, to implement this policy, the "burden of proof" for switches could be revised to require Part D plans to demonstrate the clinical benefit of changing therapies, rather than the current standard, which requires clinicians to object and justify overriding a switch. Further, plans could be required to disclose to all enrollees the details of their therapeutic switching programs (TSPs), generally, and their clinical rationale for each switching event, in particular. Additional oversight and review of TSPs by CMS could be required of CMS to raise awareness regarding the potential financial incentives that plans have to switch patients and ensure that the non-clinical nature of most switching practices are transparent in light of the impact on patient health.

In addition to switching between products of the same class, switching in the case of biosimilars will also put patients at risk unless the product is deemed interchangeable by the U.S. Food and Drug Administration (FDA). For biosimilar products that the FDA has not deemed interchangeable, additional safeguards should be considered. CMS should implement new patient protections to ensure that patients who are stable on a biologic are not adversely affected by a switch to a biosimilar. Protections could include a requirement that Part D plans obtain the express consent of the clinician before switching a patient. CMS could also require Part D plans demonstrate that a switch to a biosimilar would not lead to adverse clinical outcomes.

Background on Care Coordination in Oncology

In 2012, those aged 65 and older accounted for 880,000 of the 1.6 million new cases of cancer. In addition, the estimated number of cancer survivors over age 65 will increase by 42% over the next decade.[7] Given the number of patients diagnosed with cancer and the increased survival rate, we encourage the work group to consider policies that improve the coordination of care for these patients. One study, though not specific to oncology, cites inadequate care coordination to have caused between $25 and $45 billion in wasteful spending in 2011 alone due to avoidable complications and unnecessary hospital readmissions.[8] Specific to oncology, early results from a patient-centered oncology medical home pilot showed that emergency department visits at the practice fell by 68% demonstrating coordinated care for oncology patients saves money and creates efficiencies.[9]

Care coordination can encompass many things. For example, patients undergoing treatment for cancer rarely receive a written plan of care that explains the diagnosis, the treatment plan, possible symptoms due to therapies provided, and expected outcomes. Care plans that highlight these key milestones are essential resources for patients, their caregivers, and healthcare providers alike in that they assure clear communication, potentially streamline management, and improve outcomes for the patient. In addition, a care plan will ensure the patient's goals and value of treatment are understood by all members of the treating medical team, which may range a course of disciplines including oncologists, surgeons, radiologists, hematologists, psychologists, case managers, and others. Care coordination may also serve to reduce potential duplicate testing procedures and improve medication therapy management. Lastly, given the complexity of treatment and the amount of new and unfamiliar information a patient must retain during an initial consultation and throughout the course of care, the value of care coordination cannot be underscored enough.

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[7] American Cancer Society Cancer Action Network. Lifeline: Why cancer patients depend on Medicare for critical coverage. http://www.acscan.org/content/wp-content/uploads/2013/06/2013-Medicare-Chartbook-Online-Version.pdf Last accessed June 2015.

[8] Rachel Burton, "Health Policy Brief: Care Transitions," Health Affairs, September 13, 2012.

[9] Sprandio, J. D. (2012) Oncology patient–centered medical home. Journal of Oncology Practice, 8(3), 47s-49s.

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Proposed Solution

AbbVie encourages the work group explore opportunities to provide resources to health care providers to ensure care coordination is a priority for patients with a cancer diagnosis. While care coordination may encompass a variety of things, at minimum it should ensure a clear plan of care is developed and reviewed regularly between the medical teams, the patient, and his/her caregiver. Currently, there are limited to no reimbursement mechanisms in place to provide this valuable service throughout all aspects of the care continuum. While we recognize and applaud the Institutes of Medicine and the Center for Medicare & Medicaid Innovation which have begun to explore the value of care planning and shared decision-making, the likely outcomes will take years to be implemented for all Medicare beneficiaries.

Again, thank you for your commitment to advancing policy that supports improving care for some of Medicare's most vulnerable patients, those with chronic conditions. AbbVie's Government Affairs team stands ready to work with you. Should you have any questions, please contact Steve Scango (202.383.9613) or Catherine Ferguson (202.383.9616).

Sincerely,

Michael D. Boyd
Vice President, Government Affairs