MRx TREND ALERT

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YOUR QUARTERLY SOURCE FOR KEY TRENDS

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CORPORATE SOCIAL RESPONSIBILITY IN PHARMACEUTICALS

In the retail world, businesses have used select cause-related campaigns to sell their products for many years—think donating a few dollars at a restaurant or pet-food store for a relevant charity or pink products where a portion of the proceeds benefits a particular organization. However, more and more companies are taking this approach with their products in an attempt to entice and acquire customers, particularly those of younger generations. According to one survey, 91% of millennials are more likely to switch brands to one that actively practices "corporate social responsibility" (CSR) compared to 85% of the general population. Targeting millennials, who comprise one-quarter of the population, appears to be a good strategy, and, certainly, the population feels positively toward CSR.

Pharmaceutical companies are beginning to jump on this bandwagon, particularly in light of select manufacturers (e.g., Turing Pharmaceuticals, Mylan) that have been media targets for what some consider price gouging for their products. Some groups are targeting affordable drugs by creating competition as non-profit pharmaceutical companies. One 501(c)(3) organization, Medicines360®, formed in 2009, focuses on women's health. Their mission, "to expand access to medicines for women regardless of socioeconomic status, insurance coverage, or geographic location," is furthered by reinvestment of partnership proceeds to support an affordable price to public sector clinics. Their current key partnership in the United States (US) is with Amgen, the manufacturer of Liletta®, a levonorgestrel intrauterine device (IUD) approved in 2015. Likewise, a group of health systems representing more than 450 hospitals in the US launched a not-for-profit generic drug company in 2018 with the intent to make generic medications more available. Their strategy focuses on utilizing direct or contract manufacturing, stabilizing supply, and improving affordability by introducing competition.

"Some groups are targeting affordable drugs by creating competition as non-profit pharmaceutical companies."

Similarly, Medicines Development for Global Health (MDGH), an Australian-based, not-for-profit biopharmaceutical company established in 2005, strives to tackle health inequity by developing medicines for neglected diseases. After securing funding, including capital from the Global Health Investment Fund, and in collaboration with the World Health Organization's (WHO) Special Program for Research and Training in Tropical Diseases, MDGH's moxidectin, an oral anthelmintic, was approved for the treatment of river blindness in adolescents and adults. While not directly influencing price via competition, MDGH also targets drug availability for those needing treatment.

Despite a 2014 Consumer Reports article citing increasing skepticism toward the donations with a purchase strategy, this design remains relevant in the retail, and now pharmaceutical, world. While these products may not come with a promise of a donated pair of shoes, the organizations do pledge to reinvest profits to tackle challenges associated with access to healthcare. ■

BIOSIMILAR BULLETIN: CURRENT COUNTS

Over 3 1/2 years after the approval of the first US biosimilar, the biosimilar approval count is at 14; however, only 6 have launched. Biosimilars can offer cost savings and increased access, but litigation hurdles impede commercial availability. The table below depicts the state of approvals versus launches in the US. Biosimilars in green have launched on the market. ■

BIOSIMILAR (NONPROPRIETARY NAME)/ MANUFACTURER	ORIGINATOR (MANUFACTURER)
Zarxio® (filgrastim-sndz)/Sandoz	Neupogen® (Amgen)
Inflectra® (infliximab-dyyb)/Pfizer	Remicade® (Janssen)
Erelzi™ (etanercept-szzs)/Sandoz	Enbrel® (Amgen)
Amjevita™ (adalimumab-atto)/ Amgen	Humira® (Abbvie)
Renflexis® (infliximab-abda)/Merck	Remicade (Janssen)
Cyltezo® (adalimumab-adbm)/ Boehringer Ingelheim	Humira (Abbvie)
Mvasi™ (bevacizumab-awwb)/ Amgen	Avastin® (Genentech)
Ixifi™ (infliximab-qbtx)/Pfizer	Remicade (Janssen)
Ogivri™ (trastuzumab-dkst)/Mylan	Herceptin® (Genentech)
Retacrit™ (epoetin alfa-epbx)/ Pfizer	Epogen® (Amgen) Procrit® (Janssen)
Fulphila™ (pegfilgrastim-jmdb)/ Mylan	Neulasta® (Amgen)
Nivestym™ (filgrastim-aafi)/Pfizer	Neupogen (Amgen)
Hyrimoz™ (adalimumab-adaz)/ Sandoz	Humira (Abbvie)
Udenyca™ (pegfilgrastim-cbqv)/ Coherus	Neulasta (Amgen)

DID YOU KNOW? – CMS CODING DECIPHERED

When it comes to billing, the Centers for Medicare & Medicaid Services (CMS) does not oversimplify things; however, there is a method to the madness. In 1978, the Healthcare Common Procedure Coding System (HCPCS), or "hick-picks," was established to provide a standardized coding system to describe items and services, although its use was voluntary at the time. In the late 1990s and early 2000s, these codes were subsequently required for transactions with the implementation of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

HCPCS consists of 2 primary levels of codes: level I – numeric Current Procedural Terminology (CPT) codes, which are usually related to physicians' services (e.g., office visits); and level II – alphanumeric codes, which typically apply to products, supplies, and procedures. HCPCS also had a third component, level III codes, which were comprised generally of local codes for use in specific programs and jurisdictions, but these have since been eliminated. The 5-digit CPT codes are maintained by the American Medical Association (AMA), which oversees the decision to add, delete, or revise CPT codes. The alphanumeric codes within level II consist of 16 categories with assigned letters A through V, such as enteral and parenteral therapy (B-codes), durable medical equipment (E-codes), and non-orally administered drugs or chemotherapy (J-codes). The assigned letter is then followed by 4 numeric digits, forming a 5-digit code, to identify the particular drug, including dose if appropriate. Permanent HCPCS codes are updated annually for a January 1 implementation. Notably, level II codes also consist of select temporary codes, such as Q-codes, that identify services which do not currently have a level II code but are needed for claims processing. These are assigned by CMS on a temporary basis; once a permanent code is assigned, the Q-code is then deleted and cross-referenced. These codes can be added, changed, or deleted on a quarterly basis and are usually implemented within 90 days of the decision. For instance, in July 2018, temporary Q-codes went into effect for the use of buprenorphine extended-release injection (Sublocade™) with 2 dose specifications, which was approved in late November 2017. While waiting for a temporary code, a miscellaneous code may be used for a few months; however, this can lead to difficulty in billing, particularly without detailed drug information, such as a National Drug Code (NDC), to enable more accurate billing and reimbursement. Consequently, vigilant quality assurance is required in this interim period.

While it may not be simple, HCPCS provides a systematic approach to communicate claims data, including the ability to adapt with temporary codes, helping to streamline the over 5 billion claims processed by insurers each year. ■

KEEP ON YOUR RADAR: NEW ECRI GUIDELINE PORTAL LAUNCHES

On July 16, 2018, as the summer sun blazed, the sun set over the National Guideline Clearinghouse™ (NGC) due to federal funding cuts. Created in 1998 by the Agency in Healthcare Research and Quality (AHRQ), in partnership with the AMA and the American Association of Health Plans (now America's Health Insurance Plans), the NGC was an invaluable central repository of clinical practice guidelines and provided NGC's valuable guideline summaries. The informative guideline.gov website, which was free and open to the public, boasted approximately 200,000 visits per month, mostly from healthcare professionals. While AHRQ is exploring options to carry on the important work of the NGC, the Emergency Care Research Institute (ECRI), an independent non-profit organization that developed and maintained NGC's website, launched a new site to replace NGC on November 19, 2018. The ECRI Guidelines Trust™ on ecri.org/guidelines will house unbiased summaries of guidelines plus scorecard evaluations on Transparency and Rigor Using Standards of Trustworthiness compared to the Institute of Medicine standards for trustworthiness. Many evidence-based guidelines with briefs and score cards will be available and ECRI plans to add new content regularly. In 2019, additional Trust features, such as advanced searches, an enhanced user interface, and support for guideline implementation and decision-making, are expected. The new site is free with registration; however, in its next phase, ECRI could charge fees for special features. ■

MEDICAL PHARMACY CORNER

HARNESSING UTILIZATION MANAGEMENT TOOLS IN MEDICARE ADVANTAGE

Medicare Advantage (MA) is a Medicare health plan option administered by private health insurers rather than the federal government. One of the goals of MA compared to traditional Medicare is to offer members extended services at lower costs. MA plans are required to follow regulations set forth by CMS regarding administration of the Medicare benefits. Historically, these regulations have somewhat limited the ability of private health insurers to exercise standard utilization management techniques designed to ensure cost effectiveness of the benefit.

On August 7th of this year, CMS released a memo rescinding one of these prior restrictions. Effective January 1, 2019, MA plans will be allowed to utilize step therapy for medications billed under Medicare Part B. The majority of medications billed under Medicare Part B are administered by providers in their office or in a hospital outpatient setting and are often given as intravenous (IV) infusions. Step therapy, which is often utilized for other types of pharmacy benefits (e.g., Medicare Part D), requires a preferred, alternative medication to be utilized prior to the use of the less preferred medication. Consistent with other CMS guidelines for step therapy, this can include off-label indications as long as they are supported by compendia. In the memo, CMS acknowledges, "that the use of step therapy is a recognized utilization management tool" and further states, "the allowance of step therapy practices for Part B drugs will help achieve the goal of lower drug prices while maintaining access to covered services and drugs for beneficiaries."

CMS is requiring any MA plan instituting step therapy to also offer a patient-oriented care coordination program. These care coordination programs will, at a minimum, provide patients with interactive consultations regarding their medication regimen. These consultations may involve medication review and reconciliation, provision of educational information and materials, and/or counseling regarding medication adherence strategies. In order to incentivize patients to participate in such a program, MA plans are directed by CMS to pass along at least half of the resulting savings from these programs to the patient. Based on existing statutes, these savings rewards cannot be offered to patients in the form of either cash or monetary rebates such as reduced cost sharing. Instead, these rewards must be in the form of gift cards or "other items of value to all eligible enrollees."

While many MA plans welcome the opportunity for use of additional management strategies, the release of the August memo has given plans little time to prepare to institute such changes beginning as early as January. While some large insurers offering MA plans have announced details regarding their plans to institute the Part B step therapy requirements beginning in January, many other MA plans are taking a "wait and see" approach to allow time for more questions to be answered and more infrastructure to be established in order to institute such a program. ■

PIPELINE REPORT: 4TH QUARTER 2018 AND 1ST QUARTER 2019

DRUG MANUFACTURER	CLINICAL USE	ANTICIPATED DATE	PROJECTED MARKET IMPACT
Select Branded Pipeline Agents: Potential New Emerging Expenses for Health Plans			
glasdegib Pfizer	Acute myeloid leukemia (AML)	December 2018	First oral smoothened receptor inhibitor; demonstrated improved median overall survival in BRIGHT 1003; Orphan Drug; Priority Review
brexanolone Sage	Postpartum depression (PPD)	December 19, 2018	IV $GABA_A$ receptor modulator administered as a one-time dose; demonstrated significant reductions in depression rating scale as early as 24 hours after treatment and maintained through 30 days in Hummingbird trials in moderate to severe PPD; Breakthrough Therapy; Priority Review
sacituzumab govitecan Immunomedics	Metastatic, triple-negative breast cancer	January 18, 2019	IV antibody conjugate targeting Trop-2 for patients who have received ≥ 2 prior therapies; Breakthrough Therapy; Fast Track; Priority Review
cladribine Merck	Relapsing forms of multiple sclerosis (RMS)	January 30, 2019	Oral, lymphocyte-targeting purine nucleoside analogue; reduced annual relapse rate with sustained response at 2 years in CLARITY trial; may offer treatment in relatively few doses with unique mechanism of action; Fast Track
Select New Generics/Patent Expirations			
mesalamine generic for Allergan's Canasa®	Ulcerative colitis	December 15, 2018	Settlement agreement with Mylan; eligible for 180-day exclusivity; US sales of $244 million in 2017
pimecrolimus generic for Valeant's Elidel®	Atopic dermatitis	December 27, 2018	Expiration of pediatric exclusivity; Actavis/Teva submitted Abbreviated New Drug Application (ANDA); US sales of $186 million in 2017
sofosbuvir/ledipasvir generic for Gilead's Harvoni®	Hepatitis C virus (HCV) infection	January 2019	Authorized generic (AG) from Asegua Therapeutics announced in September 2018; ANDA-approved generic competition not expected for several more years; US sales of $5.55 billion in 2017
sofosbuvir/velpatasvir generic for Gilead's Epclusa®	HCV infection	January 2019	AG from Asegua Therapeutics announced in September 2018; ANDA-approved generic competition not expected for several more years; US sales of $2.75 billion in 2017
Select Biosimilars/Follow-on Products			
rituximab (Truxima) – biosimilar to Genentech's Rituxan® Teva/Celltrion	Non-Hodgkin's lymphoma (NHL) indications	November 30, 2018	IV CD20-directed cytolytic antibody; product launch may be delayed due to regulatory hurdles and settlement agreements; in October 2018, an FDA advisory committee recommended approval of Truxima for 3 NHL indications of the reference product; Rituxan had $4.04 billion in US sales in 2017
trastuzumab (Herzuma) – biosimilar to Genentech's Herceptin® Teva/Celltrion	HER2-positive breast cancer; HER2-positive metastatic gastric or gastroesophageal junction adenocarcinoma	December 18, 2018	HER2/neu receptor antagonist; launch may be delayed due to regulatory hurdles; Herceptin had $2.8 billion in US sales in 2017