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Enhanced Steps to Combat the Opioid Epidemic

While the opioid epidemic has received attention for the past handful of years, significant steps have occurred in 2016 to combat this public health concern. In March 2016, the Centers for Disease Control and Prevention (CDC) published guidelines on the use of opioids for the treatment of noncancer chronic pain. The CDC's guidelines provide support to prescribers and context for general dosing from pain management experts.

In July 2016, Congress passed the Comprehensive Addiction and Recovery Act (CARA). Notable components of this landmark bill include expansion of diversion programs focusing on treatment, expansion of prescription drug disposal programs, and expanded use of naloxone (an opioid antagonist for reversal of a narcotic overdose). CARA also allows for partial fills of opioids when not prohibited by state law and encourages abuse-deterrent opioid development by making these medications exempt from classification as "line extensions" when calculating Medicaid rebates. It also provides grants to states for select activities aimed to combat this epidemic; however, funding for these provisions is not a component of CARA. In addition to CARA, the U.S. Health and Human Services (HHS) Secretary also announced new actions to combat the opioid epidemic in 2016 building on their HHS Opioid Initiative. Some components include expanded access to medication assisted treatment and a proposal to remove components regarding pain management from their Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. This survey change is intended to prevent the perception of financial pressure to overprescribe opioids during inpatient stays or upon discharge.

Local governments, businesses, and communities have also made strides to curb the opioid crisis. Some states allow for dispensing of naloxone without a prescription, and select retail pharmacy chains have announced expanding availability of naloxone in these states. Similar to HHS's proposal aimed to limit unnecessary use related to acute pain management, one hospital in New Jersey launched its Alternatives for Opiates Program (ALTO℠) in 2016. The program uses alternative protocols with non-opioid treatments to limit opioid prescribing by emergency room providers. Similarly, the Virginia Hospital and Healthcare Association created guidelines in 2016 regarding the use of opioids in the emergency department. In general, the guidelines discourage prescribing opioids for use upon discharge as well as unnecessary use during the visit. These guidelines and initiatives aim to encourage providers to consider alternatives and limit pressure on providers to prescribe opioids.

> ***"Notable components of this landmark bill include expansion of diversion programs focusing on treatment, expansion of prescription drug disposal programs, and expanded use of naloxone (an opioid antagonist for reversal of a narcotic overdose)."***

While there is still much progress to be made to reduce the misuse and abuse of opioids and their consequences, enhanced programs may provide additional measures to curb this epidemic.

INSIDE THIS ISSUE

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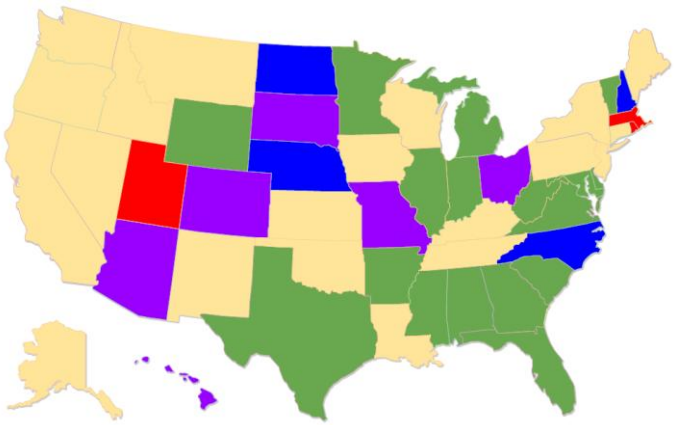
Telemedicine: The Wave of the Future? – Part 1

Telemedicine or telehealth, terms often used interchangeably, involves the use of technology to deliver healthcare to a remote location. Think of it as a virtual house call. With the advanced technology of today including e-mail, mobile applications, and text messaging, there are many opportunities for telemedicine. These might include video conferencing between a patient and physician, local physicians consulting with remote specialists by way of shared electronic images, or data from patient monitoring devices being transmitted to a healthcare provider. Is telemedicine the wave of the future? There seems to be little doubt that telemedicine has the potential to expand access and convenience, but questions remain about quality and cost. Advocates of telemedicine, such as the American Telemedicine Association, cite research demonstrating the cost effectiveness and efficacy of telemedicine; however, others question whether telemedicine may increase unnecessary healthcare utilization. If telemedicine services are just an addition to current services, rather than a replacement, overall costs may increase. To date, reimbursement seems to be the biggest hurdle for wide-scale adoption of telemedicine; although, this seems to be changing. Telehealth is often divided into several classifications; currently the most commonly reimbursed form of telehealth is live video. Many individual states have telemedicine parity laws, mandating private insurers provide coverage for remote consultations, reimbursed at the same rate as in-person visits. Self-funded employer plans have been enthusiastic adopters of telemedicine, as they claim it reduces employee absenteeism. On a federal level, Medicare's regulations surrounding telemedicine also seem to be taking tentative steps forward. Currently, Medicare only allows the use of telemedicine when the patient is in an "eligible facility" (not the patient's home), and that facility must be located in a designated rural area; however, newly added telemedicine procedure codes may signal a shift towards expansion of telemedicine for Medicare beneficiaries. As is commonplace with Medicaid programs, telehealth policies vary significantly from state to state. Despite this, 47 states and the District of Columbia provide reimbursement for at least some form of telemedicine in their Medicaid fee-for-service programs. In addition to reimbursement difficulties, quality of care associated with telemedicine has also come into question. The majority of research has demonstrated no meaningful difference in terms of diagnosis accuracy and formulation of an effective treatment plan with telemedicine compared to face-to-face visits; however, at least one study utilizing "secret shoppers" raised concerns. Posing as actual patients seeking treatment at different telemedicine sites, the authors found several sites misdiagnosed some conditions.

While reimbursement and current regulations remain the most significant barriers to widespread adoption of telemedicine, with potential cost savings and heightened demand for convenience, it appears telemedicine will become an increasingly key modality in the delivery of healthcare. The next edition of the *Quarterly Trend Advisory* will explore Part 2 of this series focusing on telepharmacy.

State Medicaid Policies – Live Video Telehealth



Geographic restrictions – telehealth reimbursement limited to certain geographic areas; most commonly rural or underserved areas

Limited sites – telehealth reimbursement limiting the originating site of care to specific facilities which often (but not always) exclude the patient's residence

- No policy
- Geographic restrictions
- Limited sites
- Both geographic restriction & limited sites
- Reimbursement for live video telehealth for at least some services

Adapted from: The National Telehealth Policy Resource Center.

Available at: http://cchpca.org/sites/default/files/resources/50%20State%20FINAL%20April%202016.pdf

The Hope for Personalized Medicine in Behavioral Health

Pharmacogenomics aims to improve efficacy and safety of medications by tailoring them to an individual patient's genetics. While its role has been touted as the future of drug therapy for some time, the clinical application of pharmacogenomics to personalize drug therapy is still limited.

"In the area of behavioral health, companies are now capitalizing on the ability to test a patient's genome to guide therapy."

The use of pharmacogenomics has been explored in several disease states with the goal of avoiding toxicity or improving efficacy. For example, in the treatment of human immunodeficiency virus (HIV), prescribers test for HLA-B*5701 to determine if patients are candidates for abacavir (Ziagen®), since patients positive for this allele are more likely to have a potentially life-threatening hypersensitivity reaction. Similarly, patients with acute coronary syndrome who are carriers of 2 CYP2C19*2 alleles, may experience reduced efficacy with clopidogrel. As knowledge of pathophysiology expands to encompass the impact of genetic variations, manufacturers are applying this information to drug development as well.

In the area of behavioral health, companies are now capitalizing on the ability to test a patient's genome to guide therapy. Assurex Health offers multiple GeneSight® tests to predict a patient's response to medications, including antidepressants, antipsychotics, and medications for attention-deficit hyperactivity disorder (ADHD). For instance, their psychotropics test assesses a patient's genetics in relation to drug metabolism, as well as the drug's effect on the body. A personalized report is developed to identify medications that may be used as directed and those with moderate or significant gene-drug interactions. The report also provides clinical considerations, and genetic counselors and pharmacists from Assurex Health are available to discuss the report with the prescriber. Similarly, Genomind offers their Genecept Assay®. In addition to select pharmacokinetic genes, it tests for genes related to particular brain receptors and enzymes that may impact a drug's mechanism of effect. While there is some published data demonstrating an improvement in symptom control compared to standard of care, evidence for use is limited at this time.

The goal of these tests is to provide a better clinical baseline to predict treatment response and tolerability, particularly in challenging disease states. The hope with pharmacogenomics is that it will become a key strategy to improve efficacy, reduce toxicity, and provide cost savings by personalizing medication therapy.

Keep on Your Radar: The High Cost of Convenience—Pharmaceutical Kits

Many people are willing to pay more for convenience; grocery stores who sell pre-diced vegetables figured that out long ago. Recently, pharmaceutical manufacturers seem to be capitalizing on this trend of "convenience." In the past year, several new products have been introduced that package separate pharmaceutical products together as a "kit" and then place an much higher price tag on the kit. A common approach is adding a medication approved for over-the-counter (OTC) use and packaging it with an approved prescription product. Whether these kits truly improve patient convenience or provide any added benefit is a reasonable question. One example is Ticanase™, marketed by PureTek and introduced in January 2016. Ticanase is a kit containing prescription fluticasone propionate nasal spray used for seasonal allergies (wholesale acquisition cost [WAC] = $22.00) and an over the counter saline nasal spray (similar product WAC = $2.74). The price for the kit? $3,783.22. Another example is DS Prep Pak marketed by Alvix Laboratories. DS Prep Pak contains diclofenac sodium 1% topical gel (WAC = $38.46), approved for the relief of pain associated with osteoarthritis. Included in the DS Prep Pak are 20 topical antiseptic wipes and 20 sterile gloves (both OTC products available for under $5 each); adding up to an approximate cost of $54 for the individual components while the WAC of DS Prep Pak is $419.29. Some of these new kits are not federally rebated and, therefore, might automatically be excluded from Medicaid formularies; however, other types of pharmacy benefits could be impacted. Payers should be aware of this new marketing approach and consider placing edits to block the use of these "convenience kits," some of which appear to offer little added convenience but are certainly expensive and may contribute to the rising cost of prescription drug benefits.

Pipeline Report: 3rd/4th Quarter 2016

Drug/Manufacturer	Clinical Use	Anticipated Date	Projected Market Impact
Select Branded Pipeline Agents: Potential New Emerging Expenses for Health Plans			
abametapir lotion (Xeglyze™) Dr. Reddy's	Head lice infestation	September 14, 2016	Kills both lice and eggs in 1 application; likely to be Rx only; studied in ≥6 months of age; may compete with Rx ivermectin 0.5% topical lotion (Sklice®), that is also a 1 time application; many other products require 2 applications 7 to 10 days apart; there are also issues of parasite resistance with some products in this class
oxycodone, extended-release (Remoxy™) Pain Therapeutics	Severe pain requiring daily, around-the-clock treatment	September 23, 2016	Abuse-deterrent, extended-release oxycodone submitted for 5 different strengths from 5 mg to 40 mg; the 5 mg dose would be the lowest extended-release dose of oxycodone on the market, which may have a niche as guidelines now encourage prescribing the lowest effective dose
lumacaftor/ivacaftor (Orkambi®) Vertex	Cystic fibrosis patients homozygous for F508del ages 6 to 11 years	September 30, 2016	Previously approved in cystic fibrosis patients homozygous for F508del who were 12 years of age and older; estimated 2,400 children in the U.S. between ages 6 and 11 years who would be newly approved to receive Orkambi
sarilumab Sanofi Regeneron	Rheumatoid arthritis	October 30, 2016	Fully human monoclonal antibody directed against interleukin-6 (IL-6), which was superior to adalimumab for treatment of RA in a phase 3 trial; will likely compete with tocilizumab (Actemra®), a currently marketed IL-6 inhibitor
Select New Generics/Patent Expirations			
ganciclovir ophthalmic gel-generic for Valeant's Zirgan®	Acute herpes simplex keratitis	September 15, 2016	Zirgan is an FDA-designated orphan drug for this indication and is protected by orphan drug exclusivity until 9/15/2016; Zirgan had $17 million in U.S. sales in 2015
estradiol vaginal tablet-generic for Novo Nordisk's Vagifem®	Atrophic vaginitis due to menopause	October 1, 2016	FDA approval granted for generic estradiol vaginal tablet 10 mcg in 2015, but a settlement agreement between Amneal and Novo Nordisk delayed launch; Amneal will have 180-day exclusivity; Vagifem had U.S. sales of $388 million in 2015
Select Biosimilars			
ABP501-biosimilar to Abbvie's Humira® Amgen	Ankylosing spondylitis; Crohn's disease; hidradenitis suppurativa; polyarticular juvenile idiopathic arthritis; psoriasis; psoriatic arthritis; rheumatoid arthritis; ulcerative colitis; uveitis	September 25, 2016	Clinical trials showed subcutaneous biosimilar ABP501 to be clinically equivalent regarding effectiveness, safety, and immunogenicity to subcutaneous Humira; although approval may occur in September 2016, product launch will be delayed due to regulatory hurdles; Humira had $11 billion in U.S. sales in 2015
GP2015-biosimilar to Amgen's Enbrel® Sandoz	Rheumatoid arthritis; psoriasis; psoriatic arthritis; ankylosing spondylitis; juvenile rheumatoid arthritis/juvenile idiopathic arthritis	September 26, 2016	Subcutaneous tumor necrosis factor alfa (TNFα) indicated for rheumatoid arthritis and other auto-immune conditions; pharmacokinetic and clinical trials confirmed bioequivalence to the originator product; product launch will be delayed due to regulatory hurdles; Enbrel had $6.6 billion in U.S. sales in 2015