Pittsburgh Business Group on Health

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PBGH Group Purchasing Solutions

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New Directions
Helping Brokers Navigate Today's Healthcare

Weight Loss Medications and New Approvals Update

Recently, the U.S. Food and Drug Administration (FDA) granted approval for two, new medications to treat weight loss:

Wegovy (semaglutide)

- Wegovy (semaglutide) is a self-injection **dosed once weekly for chronic weight management** in adults with obesity or who are overweight with at least one weight-related condition (such as high blood pressure, type 2 diabetes, or high cholesterol), for use in addition to a reduced calorie diet and increased physical activity. This is the first approved drug for chronic weight management in adults with general obesity or overweight since 2014. In clinical trials, individuals experienced as great as **15-18 percent weight loss (over an extended period of time)**

- PBM management protocols are crucial to the appropriate utilization management criteria relative to patient eligibility, dosing and administration, as well as appropriate outcomes and absence of adverse effects.

- Approximately **70 percent of American adults have obesity or are overweight** – a serious health issue associated with leading causes of death, including heart disease, stroke and diabetes.

Aduhelm (aducanumab)

- Aduhelm (aducanumab) from Biogen is the **newest drug therapy advancement approved for Alzheimer's in more than 18 years**. Alzheimer's is a disease that gradually leads to decline in cognitive function of certain brain areas, which can lead to the inability to perform daily tasks.

- There is much controversy around the clinical trial data and results, which led to an expedited FDA approval for Aduhlem. Clinical **trial data reviewed showed a reduction in brain plaques; however, this did not necessarily correspond with improved cognitive function**. Some trial evidence points to concerning serious, adverse effects, which may lead to brain swelling and brain bleeds. This potential treatment is **anticipated to cost more than $50,000 per patient annually**, and there are as many as one million potential candidates estimated to be eligible to receive treatment across the country.

Group Health Plan Reporting Requirements for Pharmacy Benefits due to Consolidated Appropriations Act (CAA) of 2021

Group health plans (self-insured employers) should be preparing for the new annual reporting requirement related to pharmacy benefits and drug costs because of the CAA, 2021.

Reports must be submitted no later than one year after the date of enactment date. Subsequent filings must be completed by June of each subsequent year.

The information reports must include the following:

- Beginning and end date of plan years.
- Number of enrollees
- Each state in which the plan is offered
- 50 brand prescription drugs **most frequently dispensed** and paid for by the plan and the total number of claims for each drug
- 50 **most costly drugs paid** for by the plan based on total annual drug spend and annual amount of spend for each drug
- 50 prescription drugs **with the greatest increase** in spend over the prior year and for each drug the percentage increase
- Total spending on healthcare services broken down by the types of costs, including (1) hospital, healthcare provider, and clinical service costs, for primary care and specialty care separately; (2) costs for prescription drugs; and (3) other medical costs, including wellness services. In addition to types of costs, spending on prescription drugs would need to be broken down by the health plan spend and the participants' and beneficiaries spend
- Average monthly premium spent by employers and employees
- The impact on premiums by rebates, fees, and any other compensation paid by drug manufacturers to the plan, with respect to prescription drugs prescribed to enrollees in the plan or coverage, including the amounts paid for each therapeutic class of drugs, and the amounts paid for each of the 25 drugs that yielded the highest amount of rebates and other compensation under the plan or coverage from drug manufacturers during the plan year.
- Any reduction in premiums and out-of-pocket costs associated with rebates, fees, or other compensation described in the preceding paragraph.

The CAA requires that the Secretary of HHS make available on the Department of HHS website a report on prescription drug reimbursements under group health plans and group and individual health insurance coverage, prescription drug pricing trends, and the contribution of prescription drug costs to premium increases or decreases under such plans or coverage in aggregate no later than 18 months after the first informational report is submitted.

Will Pharmacogenomics be the next big focus for employer's benefit programs?

The United States spends more on health care than any other country, estimates are approaching 18% of GDP. Of those studies suggest up to 30% of that spending may be considered waste. This waste can come in many forms, from over insurance, to overpayment, misdiagnosis, misaligned incentives, and outright fraud, among others.

I have spent the last 10+ years in the employer benefit space focused on solutions that will create better distribution of health insurance to minimize the inefficiencies that exist. The intention has been to maximize the employer's investment in employee's health and outcomes. Over the past 3 years I have seen the pharmacy benefit of those plans explode in terms of cost. There are several factors driving this, from the vertical integration of PBMs and consolidation to misaligned incentives that lead to over prescribing. Everyday new business models are being created to unwind the oligopoly that has been created. Today I want to focus on Pharmacogenomics (PGx) as an additional solution that is available to payers.

Pharmacogenomics is the study of the role of the genome in drug response. Its name (pharmaco- + genomics) reflects its combining of pharmacology and genomics. Pharmacogenomics analyzes how the genetic makeup of an individual affects their response to drugs. This is not new science; it was studied extensively in the 1950's; the term became popular in the 1990's and the first approved FDA PGx test was in 2005. In its simplest form it will tell a patient and prescriber based on there DNA make up if a drug will work or not. When you think of high utilizers, 5 or more therapeutics at the same time, the question becomes, how are they mixing and working together based on your specific DNA?

I recently became aware of the term ADI (Adverse Drug Interactions). **Each year 4.5 million hospital visits are attributed to ADI's**, accounting for up to 10% of direct health care cost. PGx test could eliminate 50% of ADI's. A massive improvement in efficiency but way more importantly ADI's are considered the 4th leading cause of death in the United States. Getting the drug mix and appropriate therapy right based on DNA is critical for the health and safety of employees.

Progress is being made. Many challenges exist in the infrastructure of the healthcare system to ensure prescribers have the appropriate information to ensure the best therapy will be prescribed. These pipelines are being built to make the information easily accessible at the point of care. Health plans are also starting to see the logic and efficiencies of covering the cost of a PGx test. UHC announced last year they will begin to cover this test specifically around the diagnosis of depression. **It often takes 9 weeks to determine if an anti-depression medicine is effective**, if not the cycle needs to start again with a new therapy. PGx test will eliminate that time and waste. This is just a small example but a green shoot for sure in the early adoption and coverage by health plans.

PBGH is here as a resource an advocate. We have may examples where we took an issue to a Health plan or PBM to make the logical case why a procedure or a therapy.

Upcoming Events

Annual Symposium – Stewardship 2021 • Wednesday, September 15

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*Formerly known as PBGH Services, Inc.