

First Script Prescription Benefit News for Workers' Compensation

September 2017

Drug of the Month



Cyltezo[®]

The second biosimilar for the rheumatoid arthritis drug, Humira[®], was approved by the Food and Drug Administration (FDA) on August 25, 2017. Cyltezo (adalimumab-adbm) is made by Boehringer Ingelheim and joins Amjevita[®] (adalimumab-atto), the first Humira biosimilar, which was approved for Amgen in September of last year. Both biosimilar drugs are based on the reference product from AbbVie, Humira (adalimumab), which is a biologic medication indicated in the treatment of various inflammatory conditions including rheumatoid arthritis, juvenile arthritis, ankylosing spondylitis, Crohn's Disease, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa, and uveitis. The biosimilar, Cyltezo, was FDA-approved for all of Humira's indications with the exception of hidradenitis suppurativa and uveitis.

Cyltezo is an injectable product available as 40 mg adalimumab-adbm in a 0.8 mL single-use prefilled glass syringe. The approved dosing for Cyltezo varies based on the condition being treated, but in general the drug is injected every other week for maintenance. Cyltezo is immunosuppressive in nature as it works by blocking tumor necrosis factor (TNF) within the body, a regulator of immune cells. Patients should be monitored for the occurrence of opportunistic infections during therapy as they may be at an increased risk of hospitalization or death from serious infections such as tuberculosis (TB), bacterial sepsis, and invasive fungal infections (e.g., histoplasmosis). Due to these risks, it is recommended that the patient undergo a test for latent TB before starting Cyltezo, and the patient should continue to be evaluated for active TB periodically throughout Cyltezo treatment. Patients with any active infection should not be started on Cyltezo, and live vaccines or therapeutic infectious agents should not be given with Cyltezo.

Adverse effects reported with the use of Cyltezo include infections (e.g., upper respiratory, sinusitis), injection-site reactions, headache, and rash. A severe allergic reaction known as anaphylaxis may also occur at any time during use of Cyltezo, and this occurrence would constitute discontinuation of the drug and immediate treatment.

Biosimilar products are often less costly than their biologic reference product counterparts. According to Medispan, the cost (based on AWP) for the reference biologic (Humira) is \$2,664.74/syringe. Pricing is not yet available for the two biosimilar products, Amjevita and Cyltezo, as neither product is yet available for sale. However, the drugs can be reasonably expected to follow the lower comparative price point typical of biosimilar drugs. In the future, if an injured worker is currently receiving a work comp approved prescription for Humira, this may be an opportunity to engage in a discussion with the provider regarding a switch to one of the available biosimilar medications. The prescriber would need to contact the pharmacy to expressly authorize a change from Humira to the biosimilar product, or they may simply write the prescription for the specific biosimilar medication going forward.

In any case, biosimilar medications like Cyltezo fall in the "specialty" drug category, and additional oversight is recommended due to the complex or costly nature of these types of drugs. Furthermore, the conditions treated by Cyltezo are not typically considered to be work-related as a person is genetically predisposed to have these diagnoses. The appropriateness for use of Cyltezo in relation to the work injury should be determined prior to coverage consideration.



Ask The Pharmacist

To suggest a topic, send an email to:
AskThePharmacist@cvty.us.com

Will there be less opioid medications produced next year (in 2018)?

Yes, the U.S. Drug Enforcement Administration (DEA) has announced a proposed 20% manufacturing reduction of controlled substances, including schedule II opioid pain medications, in 2018 compared to 2017.

Why limit opioid production?

The quota system established when Congress passed the Controlled Substances Act in 1970 was intended to prevent diversion from “legitimate channels of trade” of schedule I and schedule II controlled substances, which have a high potential for abuse, while ensuring maintenance of an adequate and uninterrupted annual manufactured supply of such substances for “estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks” (21 U.S.C. 826).

Such Aggregate Production Quotas (APQ) are established each year by the DEA under the authority of the U.S. Attorney General and are published in the Department of Justice Federal Register. The 2018 APQ proposal can be found [here](#) and contains a list of all basic classes affected, including common opioid pain medications (with examples of brand names containing each opioid ingredient following in parentheses for your reference) such as oxycodone (OxyContin[®], Percocet[®]), hydrocodone (Vicodin[®], Norco[®]), morphine (MS Contin[®], Kadian[®], Avinza[®]), codeine (Tylenol[®] #3), hydromorphone (Dilaudid[®]), oxymorphone (Opana[®]), tapentadol (Nucynta[®]), meperidine (Demerol[®]), methadone, and fentanyl (Duragesic[®]).

A recipe for diversion

The U.S. is in the midst of an opioid epidemic that is due in part to an exceeding abundance of circulating opioid prescription medication resulting from overprescribing. Pain is universal, however, while the U.S. makes up only a small percentage of the global population at about 5%, Americans consume the majority of the world’s opioids (80%) and 99% of the global hydrocodone supply ([Pain Physician 2010, 13:401-435](#)). This is an issue as not all opioids prescribed are being used for medical purposes, and the prescribed quantities are often such that even when the original prescription is for an intended medical purpose, any remaining pills left over and kept by the patient present ongoing opportunities for misuse or diversion.

Consider stats published by the Substance Abuse and Mental Health Services Administration (SAMHSA) from their annual [National Survey on Drug Use and Health](#) which indicates that over 11.5 million American adults reported nonmedical use of a prescription opioid over the last year in 2016. These surveys have also shown that the majority of individuals who reported nonmedical use obtained the opioids from a friend or relative. While high prescribing rates and too much supply represent only one arm of the impetus that can lead to misuse, abuse, and diversion, it is a measure that can be improved by leveraging several constraints such as following prescribing guidelines, applying evidence-based recommendations for use, and limiting the quantity of opioids prescribed or available for prescription.

Less supply/less demand

The DEA looks to data and information from a variety of sources when setting the APQ for opioids and other controlled substances. These include estimates of anticipated legitimate medical need per the FDA, estimates of retail consumption garnered from previous prescription dispensing history, manufacturers’ disposition history and forecasts, data from the DEA’s tracking systems for controlled substance transactions, and past quota histories.

The DEA cites research and sales data from IMS Health indicating a decrease in opioid demand and credits diversion control measures such as the expanding use of state Prescription Drug Monitoring Programs (aka, PDMPs or PMPs) as factors in support of a reduced opioid production supply. Other contributing influences may include a shift toward more restrictive opioid prescribing guidelines, such as those outlined in the CDC’s [Guideline for Prescribing Opioids for Chronic Pain](#).

Many guidelines promote the use of alternative, first-line non-opioid pain medications such as acetaminophen (Tylenol[®]) or nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen or naproxen before prescribing opioids. When opioids

(Continued on page 3)

(Continued from page 2)

are prescribed, guidelines stress the use of the lowest dose of opioid for the shortest possible duration and are leaning toward lesser quantities per prescription. Some states have passed opioid-specific prescribing limitations to address quantity and duration of use as well, such as legislation limiting opioid prescriptions for acute pain to an initial five-day supply. All of these considerations may have contributed to the declining demand assessed by the DEA.

What does this mean for you?

We have seen declining trends in opioid prescriptions utilized within workers' comp over the last several years; however, these opioid medications continue to be our top drug class by volume. Essentially, the impact from this reduction in APQ for 2018 should not be felt by injured workers as the DEA accounts for an observed declining demand for opioids while balancing the needs for legitimate patients. In other words, the proposed 20% reduction should already consider each manufacturer's expected requirements to produce adequate supply for the year based on the factors described above. This is not the first year we have seen a reduction in APQ. The DEA started instituting reductions last year after determining the nation's opioid supply was in excess, and a 25% reduction in opioid medications was implemented for the current year (2017) based on the DEA's proposal. In fact, a portion of the ongoing reductions are attributed to the recent elimination of a measure started in 2013 to safeguard against shortages – namely removal of a 25% buffer that had been added annually to the APQ from 2013 to 2016.

That is not to say that no safeguards remain. In the event of a shortage, the DEA has methods to adjust where warranted. Once the DEA sets the yearly APQ, individual manufacturers who apply to be included among those companies planning to make opioids for the upcoming year are given procurement quotas of their own that fit within the overall APQ. As a fail-safe, the DEA may revise a manufacturer's quota at any time during the year. So, for instance, if a manufacturing company experiences an unexpected increase in opioid sales for 2018 and requests permission to produce additional stock, or if a natural disaster strikes that affects their supply, the DEA can review the request to determine if a change is warranted and may adjust the quota accordingly.

So for 2018, there should still be plenty of opioids to go around. As always, we should remain focused on promoting best prescribing practices and ensuring that opioid utilization is medically appropriate.

First Script protects injured worker information through innovative technology

The Health Insurance Portability and Accountability Act (HIPAA) establishes the baseline for sensitive patient data protection with its Privacy and Security Rules. According to the Health & Human Services ([hhs.gov](https://www.hhs.gov)), "the Security Rule requires appropriate administrative, physical, and technical safeguards to ensure the confidentiality, integrity, and security of electronic protected health information."

In simple terms, this means at a minimum we must protect all electronic patient information, provide reasonable protection against anticipated electronic and non-electronic threats, and ensure employees are compliant.

First Script has gone beyond what the Privacy and Security Rules deem reasonable to protect data. We are light years past just using passwords and locks, and approach data protection through an innovative program that protects injured workers' data through:

- Removing Social Security Numbers (SSNs) where they are not needed or required
- Reducing or replacing SSNs by only referring to the last four digits or replacing it with an alternate unique identifier
- Protecting SSNs with encryption
- Masking demographic information in test environments



(Continued on page 4)

Social Security Number risks are costly

Keeping SSNs secure from hackers and thieves has been a security focal point for decades. A breached SSN can be devastating to a person's life and a company's reputation. Fixing it can be costly and time consuming. The average total cost of a large-scale data breach is [\\$3.62 million](#), but the panic and frustration that comes with it can't be measured in dollars.

In a recent [pulse poll](#) by [WorkersCompensation.com](#) asking about the use of SSNs on workers' compensation forms, roughly 63% of responders believed that SSN should be removed. More importantly, 91% responded that the issue was "Very Important" or "Somewhat Important." While not everyone agrees that workers' comp forms should remove SSNs, it's undeniably an important issue.

First Script's approach to data protection

- **Method One: Social Security Number ID (SSNID)**

First Script encrypted Social Security numbers on all user screens, databases, reports, and business processes where removal was not possible. In those cases, the standard SSN is replaced in our systems with a Social Security Number ID (SSNID). The actual SSN is stored in a highly protected and encrypted database, which requires a secure process to gain access.

A complex algorithm generates the SSNID, which can be a mixture of nine numbers and letters. An SSNID can be identified easily by the last three characters, which are always "ENC." For example, the algorithm could hypothetically encrypt the SSN 123-45-6789 as A49-C2-9ENC.

Our agents that talk to adjusters, case managers, pharmacists, prescribers, and injured workers have the ability to briefly decrypt the actual SSN. When the agent clicks on the SSNID, they can see the actual numbers for 10 seconds, and then it reverts to the SSNID.

- **Method Two: Encrypting Files at Rest**

The second major security update affects any files that are not in motion. "In motion" means they are not actively being imported or exported. Those files are "at rest." We fully encrypt files at rest, and refer to encrypted files at rest as being "locked." It's impossible to open a locked file without unencrypting it first, and there are security measures in place for decrypting files.

In addition to protecting injured worker information, this method secures information about our clients and providers as well, and far exceeds standard practices to safeguard sensitive info.

- **Method Three: Masking Data**

SSNs and other injured worker demographics are "masked" in environments used to test and develop product updates. Masking data scrambles it beyond recognition. Each character is replaced with another letter so there is no recognizable injured worker demographic information in our testing or development environments.

We have developed a very complex algorithm to mask information. The algorithm is so complex that depending on the length of the word being masked, character replacement can vary. For example, when the word "info" is masked, we see it as "ogni." However, when the word "information" is masked, we see it as "ognukzewuuk." This feature makes it more difficult to reverse engineer the algorithm.

First Script is committed to our clients and injured workers

First Script's dedication to cyber security is a continual effort. Data breaches can cripple a company's reputation, and the costs to fix them are increasing annually.

We value your business and take our mission to keep your data safe very seriously. If you have any questions, please reach out to your Account Manager.

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