DC MEDICAID FEE FOR SERVICE DRUG UTILIZATION REVIEW (DUR)

DHCF Department of Health Care Finance

DC MEDICIAD PHARMACY & THERAPEUTICS (P & T) CORNER

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DC MEDICAID PHARMACY & THERAPEUTICS CORNER

Next P&T Meeting: Thursday, Sept 4th 2025 @ 2pm

The last DC Medicaid Fee For Service (FFS) P & T Committee was held on June 5th, 2025. You may review the latest DC FFS Preferred Drug List (PDL), effective July 1st, 2025 at District of Columbia Medicaid | Home. The public session of the quarterly P & T Committee is open to all, and the next meeting is Thursday September 4th, 2025 @ 2:00 pm. Visit the Prime Therapeutics DC FFS Provider Website to view all previous agendas, and meeting notices. The September meeting notice will contain registration instructions to attend the P&T public session as well as how to provide materials and/or make a presentation. The September meeting notice should be available August 1st, 2025.

INTRODUCING BIOSIMILARS

One of the most revolutionized, promising, and fastest growing topics in health care is biologics. According to the Food, Drug, and Administration (FDA), biologics are a wide range of products such as vaccines, somatic cells, blood components, allergenics, gene therapy, tissues, and recombinant therapeutic proteins. Biologics are generally complex molecules that are used to diagnose, prevent, treat, and cure disease. Biologics are isolated and produced through biotechnology in a living system (human cell, microorganism, plant cell, or animal cell). Whether biologics are utilized for gene therapy to treat genetic diseases, immunotherapy for cancer treatment, biologic immunosuppressants for autoimmune disease, etc., there are notable advantages and disadvantages/ opportunities.

There are 75 biosimilars approved by the FDA in the US as of May 2025. With the exponential growth on the market and pipeline, it is important for providers to understand the concept of biologics in healthcare. We will focus on the advantages and disadvantages of biologics along with the following terms/ topics: biosimilars, interchangeable biosimilars, and nomenclature.

Some Advantages: Biologics such as stem cell therapy, gene therapy, and immunotherapy are helping people with cancer live longer. Also, patients with chronic inflammatory and autoimmune diseases experience more success with biologics to control chronic inflammation and pain, preventing the need for corticosteroids which can become less effective with higher risk over time.

Some Disadvantages: Biologics resemble living organisms and may trigger the immune system to mistake it for an invader or infection. This trigger may activate the immune system and remove or build antibodies against the biologic. Also, the production of large and complex molecules is more complicated and sensitive to small changes in contrast to chemically synthesized small molecular weight drugs. Since the production and regulation of biologics are difficult, time to market is longer than conventional drugs and therefore are much more expensive.

Biosimilars increase access to innovative advancements in pharmaceutical treatments at potentially lower costs. The FDA defines biosimilars as, "*a biologic medication that is highly similar to and has no clinically meaningful differences from an existing FDA-approved biologic, called a reference product*". Even though biosimilars are not identical to the reference products or original biologics, the FDA requires that there are no differences between safety, effectiveness, and type of source.

Interchangeable biosimilars add another level of patient access to biologic medicine. Depending on state pharmacy laws, an interchangeable biosimilar may be substituted by a pharmacy for the referenced product without the intervention of a prescriber. However, not all biosimilars are interchangeable even though they may have the same referenced product name. The interchangeability of biosimilars must be approved by the FDA after manufacturers submit results that show no decrease in effectiveness or safety while switching.

Nomenclature for biologic/ biosimilar drugs are developed by the World Health Organization (WHO) and the FDA. The WHO assigns an international nonproprietary name (INN) which refers to the unique active ingredient component. The FDA assigns a unique suffix to the nonproprietary name. This nomenclature provides many benefits such as preventing patients from receiving a non-interchangeable biosimilar. Biosimilars have the same INN with a reference product, with the addition of a random, four-letter suffix. So, the same or identical biosimilar product will have the same assigned suffix. However, two different biosimilar products will have the same INN but a different suffix. To determine if the two different biosimilar products with the same INN but different suffixes are interchangeable, utilizing the FDA Purple Book is highly recommended.

Quite frequently in practice, a doctor's office or patient will call a pharmacy to inquire if a specific biologic product is in stock. The pharmacist or technician will usually check the refrigerator and confirm that the requested biologic is available to dispense. Only later to discover that the appeared INN or unique active ingredient component product failed at quality assurance checkpoints during the pharmacy workflow and therefore cannot be dispensed for a waiting patient and require further steps from the prescriber. Or even worse, a non-interchangeable biosimilar product with the same INN was overridden by the pharmacist at checkpoint and dispensed to the patient. In these cases, when a pharmacy receives a 'stock check' request from a patient or doctor's office, a pharmacist on duty should be notified to utilize the FDA Purple Book.

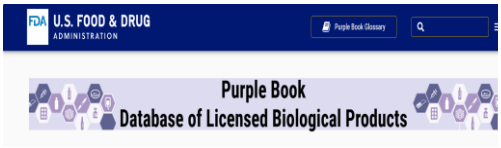

Image 1: Homepage of FDA Purple Book

PHARMACIST PRACTICE NUGGETS:

To prevent confusion for patients, prescribers, and pharmacists the following should be understood or utilized: Biologic Nomenclature, FDA Purple Book, interchangeable biosimilar state laws.

DID YOU KNOW?? The top biosimilars on the DC Fee For Service (FFS) Preferred Drug List (PDL) are Rapid Acting Insulins and Cytokine & CAM Antagonists. Also, D.C. Law 23-133, Access to Biosimilars Amendment Act of 2020 pertains to pharmacists and biosimilars. As per this law, in DC a licensed pharmacist may, with the consent of the patient, substitute an interchangeable biosimilar. The substitution must be communicated to the patient at the point of dispensing and to the prescriber.

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