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Specialty Spotlight

Purple is the New Orange

In the coming years, many top selling biological agents will lose patent protection (eg. Humira in 2016, Remicade in 2018) paving way for “generic” alternatives to appear on the market. However, the “generics” for biologics are not molecularly identical to their referenced drug (unlike small molecular drugs like Ibuprofen and Amoxicillin) due to complexities in both their structure and production process. With this, prescribers are unable to automatically use these “generics”, AKA biosimilars, as therapeutic alternatives. With many potential agents hitting the market, or more recently 2 biosimilars are awaiting FDA approval (Zarzio and Remsima), the question arises, "How can providers easily interchange these agents both safe and effectively for their patients for potential cost savings?" One answer lies in the FDA newly announced Purple Book. Similar in idea to the current Orange Book, this will provide an immediate reference for providers for therapeutic alternatives for specialty agents. Currently, the information in the book is sparce as there are no referenced biosimilars to date, but over time as more agents appear on the market, the FDA will update the information paving the way for a quick and convenient tool for healthcare providers.

Commentary:
With the rise in specialty costs, therapeutic alternatives provide an opportunity for cost savings. However, therapeutic equivalency must first be established, a challenge much more difficult with these agents due to molecular differences in brand vs generic agents. With the release of the Purple Book and its future updates, the FDA has provided the means for healthcare professionals to prescribe safely and efficiently. The FDA set up 4 standards in the book, classifying them as “not similar”, “highly similar”, “very highly similar”, and “very highly similar with fingerprint like similarity”. In addition, they place a stark emphasis on classifying each agent as a biosimilars and/or a therapeutic alternative. With these specific criteria in place, it can be safe and trustworthy for providers, eliminating one potential obstacle for the release and use of biosimilars.

Stages of Chronic Kidney Disease

Chronic kidney disease (CKD) is a prevalent condition that is easily preventable. GFR (glomerular filtration rate), which describes the rate that fluid is filtered through the kidneys, is a common indicator and measurement of CKD. CKD can be broken down into different stages defining the severity as follows:

Stage	Description	GFR- glomerular filtration rate ($ml/min/ 1.73m^2$)
1	normal kidney function but tests show early signs of damage	≥90
2	kidney damage with mild decrease in GFR	60-89
3	moderate decrease in GFR	30-59
4	severe decrease in GFR	15-29
5	kidney failure	<15 (dialysis)

Commentary:

Chronic kidney disease (CKD) is usually defined by kidney damage and a GFR (glomerular filtration rate) less than 60ml/min/1.73m2 for more than 3 months. This can be prevented or delayed through early detection and proper treatment. CKD can be classified into 5 different stages depending on the level of kidney damage and function. Kidney damage, which involves structural and functional abnormalities, can be detected through imaging and laboratory tests. In CKD stages 1 and 2, symptoms are minimal or nonexistent, but there may be signs of abnormal creatinine, urea, blood, or protein in the urine. In CKD stage 3, waste products and toxins begin to build up in the blood, possibly leading to uremia, anemia, and early bone disease. In CKD stage 4, complications of previous stages of CKD become more pronounced, with possible additional risks of cardiovascular diseases. Finally in CKD stage 5, dialysis or kidney transplant is the only option for the patient.

Source: http://www2.kidney.org/professionals/KDOQI/guidelines_ckd/p4_class_g1.htm

Are We Really Changing Hypertension Treatment?

After following JNC7 hypertension treatment guidelines for the past several years there has finally been an update; however, the new steps for treatment aren't accepted without stirring up some controversy. JNC8 was recently published this past year and can be summarized as follows:

Category	Treatment Options
Non-black	Ace-inhibitors (ACE-I), Angiotensin-receptor blocker (ARB), Calcium-channel blocker (CCB), or Thiazide-type Diuretic
Black	CCB or Thiazide-diuretic
Diabetes	ACE-I or ARB
CKD	ACE-I or ARB
Blacks with CKD (+proteinuria)	ACE-I or ARB
Blacks with CKD (- proteinuria)	CCB or Thiazide-type diuretic

Commentary:

The new JNC8 Hypertension Guidelines no longer defines prehypertension and hypertension and instead recommends treatment thresholds, goals, and therapies for those who are ≥18 years old based on latest evidence. Blood pressure goals are set based on age as randomized -controlled studies showed there was no additional benefit to setting stricter goals. Treatment is defined based on supporting evidence towards specific subgroups of the population. First line treatment options are now focused on ace-inhibitors (ACEI), angiotensin-receptor blockers (ARB), calcium-channel blockers (CCBs), or thiazide-type diuretics. Beta-blockers are not recommended for initial treatment of hypertension due to their higher rate of cardiovascular death, myocardial infarction, or strokes in comparison to the use of ARBs.

Source:James PA, Oparil S, Carter BL, et al. 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults: Report From the Panel Members Appointed to the Eighth Joint National Committee (JNC 8). JAMA. 2014;311(5):507-520. doi:10.1001/jama.2013.284427.

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