

**VOLUME 17 | ISSUE 3 | FALL 2021**

**GUEST ARTICLE: ELMC RX**



**NEW TO MARKET – CABENUVA (HIV INJECTABLE) & SEMGLEE (INSULIN BIOSIMILAR)**

Plan Sponsors are acutely aware of the increasing cost of providing critical prescription drug coverage to their employees. Part of this increase in cost is driven by the number of new medications coming to market. The FDA approved 48 novel drugs in 2019 and 53 in 2020 with the majority of these drugs classified as Specialty.

Generally speaking, these “new to market” medications are more expensive alternatives to currently existing therapies. They are frequently approved with a modification in dose or delivery method and join other medications within a specific category. Occasionally, these medications are more effective than other medications in their class, but generally, they are more expensive “me too” drugs.

ELMCRx recommends that clients monitor these new medications for six months before covering them under their prescription drug programs unless they are breakthrough therapies for conditions where no other medications exist. Here is an overview of two new medications that will likely impact employer plans in the coming months.

**Cabenuva – First Injectable HIV Agent**

Cabenuva (cabotegravir/rilpivirine) will be the first MONTHLY antiretroviral treatment for adults living with HIV. It's given as two intramuscular injections during the same visit and must be injected by a healthcare provider. The viral load suppression with Cabenuva is equivalent to the standard 3-med oral DAILY regimens, such as Biktarvy and Triumeq. Once patients achieve viral suppression and are stable, Cabenuva can be considered for patients who prefer less frequent medication dosing.

Cabenuva is a specialty medication that costs approximately \$4,000 per month for a maintenance dose compared to the current cost of \$3,300 for the widely prescribed Biktarvy or Triumeq. Cabenuva requires an initial loading dose that will add to the overall cost of treatment. Since this medication must be injected by a healthcare provider, there will likely to be additional costs associated with office visits.

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Expect to hear buzz about injecting Cabenuva every 8 weeks instead of the monthly regimen for other HIV treatments. If the 8 week interval becomes the norm, Cabenuva may become the more cost-effective option for treatment. However, Cabenuva is currently only indicated for monthly injections which makes it more costly than alternative medications. For the time being, the oral medications such as Biktarvy or Triumeq are more cost-effective treatment options. Over the past 15 months, we have seen the prevalence of HIV medication increase precipitously, becoming one of the top 4 categories for our larger clients. At this time, it is prudent to monitor the HIV medication category, as it is both increasing in cost and changing rapidly.

### **Semglee – The first “interchangeable” insulin biosimilar**

You may have heard or read about biosimilar. These medications are starting to appear on PBM formularies and are prescribed more frequently by healthcare providers. Biosimilars aren't generics. Biosimilars are “biologics”. Biologics are made from living organisms and contain larger, more complex molecules than most traditional drugs. Biosimilars are highly similar to the original or “reference” biologic. But they are not exact duplicates of “reference” biologics because it is not possible to create an exact copy.

In order to gain FDA approval, biosimilars must show similar safety, purity, and potency as the reference biologic they are mimicking. An “interchangeable” biosimilar is also shown to deliver the same clinical result as a reference biologic. Semglee was originally approved as a new brand of insulin glargine and switching required a new prescription. That’s now changing.

Semglee is the first biosimilar to demonstrate this type of evidence. It provides similar A1C score lowering at six months compared to Lantus, with a similar rate of hypoglycemia. For members taking diabetes medication, this means that Semglee should control blood sugar as well as Lantus.

Until now, pharmacies couldn't substitute the lower-cost Semglee for a higher-cost drug such as Lantus. However, an interchangeable biosimilar can often be automatically substituted without a new prescription, just like a generic. We expect many payers to prefer Semglee. It costs about \$100 per vial or \$150 for a box of 5 pens compared to Lantus at \$280 per vial or \$430 for a box of 5 pens. Depending upon the individual's specific use, this can add up to meaningful annual savings.