THE NOBLE STANDARD

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BIOLOGICAL DRUG PRODUCTS

WHAT ARE BIOLOGICAL DRUG PRODUCTS?

Biological drug products are medications produced from living organisms or parts of living organisms that have high molecular weights and are highly complex in structure. There are two classifications of biological medications – biologics and biosimilars. Biologics are the patent-holding version of the medication. As the patent holder, the manufacturer of the biologic is the one who discovered the therapy and released it to market first. Biosimilars are highly similar versions of a therapy previously approved by the Food and Drug Administration (FDA). Manufacturers of biosimilars are able to market their version of the drug after the original manufacturer's patent and exclusivity expire.

HOW ARE BIOSIMILARS DIFFERENT FROM BIOLOGICS?

Biosimilars are highly similar, but not identical to, their biologic counterpart, or reference product. While these medications are not exact copies of the reference product, they share similar structural and functional pharmacologic properties. Biosimilars show no clinically meaningful differences in the safety, purity, potency, and – in some measurements – efficacy to their biologic counterparts. For a biosimilar to be approved by the FDA, manufacturers must demonstrate that the molecule has similar characteristics and similar efficacy to the original reference biologic agent.

ARE BIOSIMILARS THE SAME AS GENERIC MEDICATIONS?

Like biosimilars, generic medications are a version of a previously FDA-approved drug. Neither biosimilars nor generics can be marketed until the patent and exclusivity on the original expire. Biosimilars and generics both offer a more affordable treatment option for patients than their biologic and conventional counterparts. Despite sharing several similarities, biosimilars and generics are not the same. Biosimilars are a biological product, thus cannot be made identical to their reference product. Generics are a conventional, chemical drug and can be synthesized to be an exact copy of their brand-name counterpart. A pharmacist can substitute a generic drug for a brand-name drug, but the same cannot be done for biosimilars, because they are

CONTINUED ON PAGE 2

CONTINUED FROM PAGE 1

not identical. Providers must specify the biosimilar product on a prescription.

ARE BIOSIMILARS SAFE?

Yes! Biosimilars must be approved by the FDA prior to being released to the public. The FDA has developed strict regulatory guidelines for the evaluation and approval of biosimilars with regards to their physical, chemical, and clinical traits. A biosimilar will only be approved by the FDA if it is identical to its reference product in the mechanism of action, route of administration, dosage form, and strength.

HOW ARE BIOSIMILARS ADMINISTERED?

Biosimilars are used to treat complex, chronic conditions such as psoriasis, Crohn's disease, ulcerative colitis, arthritis, cancer, and more. Due to their complex structure and makeup, biosimilars are typically administered via intravenous (IV) infusion or subcutaneous/intramuscular injection. These routes preserve the stability and efficacy of the drug, which may not be possible in an oral form.

WHAT ARE THE SIDE EFFECTS OF BIOSIMILARS?

Like any medication, there are possible side effects when taking a biosimilar. Biosimilars have the same potential side effects as their reference biologic medication. Because biosimilars are typically administered via IV or injection, there may be reactions at the IV or injection site. Such reactions may include redness, swelling, itching, and pain. Infusion reactions may also be more serious, requiring prompt treatment, and include: breathing difficulty, fever, chills, chest pain or tightness, and anaphylaxis.

WHAT PROGRAMS DOES NOBLE HEALTH SERVICES OFFER TO PATIENTS TAKING BIOSIMILARS?

- **Clinical Management Programs**

  Noble Health Services has a knowledgeable, dedicated clinical team responsible for administering our state-of-the-art Clinical Management Programs.

  Most Noble patients are automatically enrolled in the Clinical Management Program for their condition and treatment plan when their prescription is sent to Noble. Throughout their treatment, patients receive ongoing education and support from our clinical team.

- **Injection Training**

  As part of our Clinical Management Programs, patients have the option to receive injection training from a member of our clinical team. Injection training readies patients to safely administer their own injections.

- **Free Ancillary Supplies**

  Noble Health Services' patients receive free ancillary supplies with their prescriptions, as needed. For patients on a biologic or biosimilar, this means that Noble provides syringes, alcohol swabs, bandages, and sharps containers at no additional charge.

- **Copay and Benefits Assistance**

  Biologics and biosimilars cost more than a conventional prescription. To ease the financial burden, Noble Health Services offers copay and benefits assistance. Through the help of copay and patient assistance programs and charity organizations, our team can lower the out-of-pocket price of the prescription.

- **Powerful, Patient-Focused Care**

  Additionally, Noble Health Services offers patients the following benefits to assist with managing their condition:

  - Fast, Free Delivery
  - 24/7/365 Availability
  - Automated Refill Reminders
  - Refills by Text
  - And More