HUDDLE CARD
BIOSIMILARS

Biosimilars

Biosimilars are a type of medication that are highly similar, but not identical, to an already FDA-approved biologic, known as the reference product. They are not generic drugs, which are exact copies of traditional chemical drugs. Instead, biosimilars are made from living organisms and have small, naturally occurring variations that have no clinically meaningful difference and do not affect the safety, efficacy, purity, or potency of the product. The Food and Drug Administration (FDA) has a rigorous process for approving and monitoring these medications to ensure consistent quality. According to the FDA, a biosimilar's name is a combination of a core name (from the reference product) and a distinguishing suffix.

Examples

Biosimilar Name	Reference Product
Mvasi® (bevacizumab-awwb)	Avastin® (bevacizumab)
Udenyca® (pegfilgrastim-cbqv)	Neulasta® (pegfilgrastim)
Ruxience® (rituximab-pvvr)	Rituxan® (rituximab)
Kanjinti® (trastuzumab-anns)	Herceptin® (trastuzumab)

Benefits

- Used in the treatment of various medical conditions and diseases
- Prescribed for the same conditions as their reference products
- Just as safe and effective as their reference products
- Can be less expensive, which may improve access for patients

Limitations

- Complex manufacturing can limit the number of available biosimilar options for certain biologics
- Approval process requires rigorous and extensive comparison to the reference product, which can be time consuming and costly.
- Interchangeability—none of the currently approved biosimilars used in oncology are designated as interchangeable at this time, meaning the prescriber must specifically choose a biosimilar.
- Perception and acceptance—patients or healthcare providers may be skeptical regarding the safety and efficacy of the medication. Educating patients *prior* to administration of the biosimilar is key.

Patient and Caregiver Education Considerations

Educate patients about biosimilars. Ensure that they understand why these drugs are used and that they are just as safe and effective as their reference products. Nurses and providers should have a conversation with patients and caregivers, relaying medication information, what to expect during treatment, side effects, home medications for side effect management, discharge instructions, when to notify the healthcare team of adverse effects, and emergency contact information for providers.

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More Information

For more information on biosimilars, use the ONS resource here: Biosimilar FAQs

References

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