A Practical Approach to Biosimilar Implementation

SUGGESTED CONSIDERATIONS FOR P&T COMMITTEES

The following is a list of considerations for P&T when evaluating a biosimilar for formulary inclusion.

Key Facts on Biosimilars[1,2]

- A biosimilar is a biologic that is highly similar to the reference product with **no clinically meaningful differences** in terms of the **safety, purity, and potency**
- A biosimilar is produced by a living cell, not a chemical process
- The biosimilar approval process represents a paradigm shift, with robust analytical characterization establishing a high degree of similarity to a reference biologic
  - This reduces the need for extensive clinical testing
- Biosimilars may have the potential to increase access to biologic therapies and provide savings and efficiencies to healthcare systems. For more information and to access a digital version of this list, please visit PfizerBiosimilars.com

Biosimilar Efficacy and Safety Considerations[1-5]
Comparative Efficacy and Safety Data
Studied indication/population
Trial designed to discover clinically meaningful differences with the reference biologic
Data reported from clinical studies used to support biosimilarity show no clinically meaningful differences in:
Efficacy compared to reference biologic
Safety and immunogenicity compared to reference biologic
PK/PD studies compared to reference biologic
Totality of evidence used to establish biosimilarity with the reference biologic
Extrapolated Indications from the Reference Product
MOA for extrapolated indication is the same
If not the same, additional convincing data are provided
Surrogate markers in clinical efficacy data support extrapolation
PK/PD data support extrapolation
Safety and immunogenicity data support extrapolation
Totality of evidence submitted to the FDA

Interchangeability and Substitution
Is the biosimilar designated as interchangeable by the FDA?
Has the state adopted legislation on the substitution of biosimilars affecting this practice/institution?

Manufacturer Considerations[3,6]
Manufacturer History and Portfolio
Institution history with the biosimilar manufacturer
Manufacturer portfolio and pipeline in the therapeutic area indication
Manufacturer supply chain
Manufacturer patient support program

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Pharmacoeconomic Considerations[3,5,6-8]
Potential Budget Impact
Reduction in current spend
Manufacturer billing and coding support
Biosimilar has a designated HCPCS code
Biosimilar is 340B Drug Pricing Program available
Patient Access
Any prior authorization requirements
Patient co-pays relative to reference biologic
Patient support programs are available

Operational and Institutional Considerations[3,5,6,9,10]
Pharmacovigilance
Biosimilar post-marketing study
Biosimilar REMS program
REMS program is standardized with the biologic's REMS program
Electronic Health Records (EHR)
Tracking systems are able to distinguish between reference biologic and biosimilar
Staff trained on naming differences between reference biologic and biosimilar
Tracking policies in place to manage transitions of care and track products
Operations
Differences in preparation or administration compared with other therapies
Cost considerations/savings due to operational changes (storage, preparation, administration)
Patient, HCP, and Staff Education
Educational materials have been developed
HCPs and staff are educated on biosimilars
Patients will need to be educated on:
Understanding/acceptance of a biosimilar as required by state law
Potential changes in the patient experience vs. previous therapy
Changes in co-payments or insurer policies
Patient support programs
Product Storage
Containers, packaging, and labeling are easy to read
Differences in packaging from the reference product
Differences in storage and handling requirements from the reference product
Par levels have been established
Storage practices designed to help prevent dispensing errors

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