# Biosimilar Implementation: Potential Best Practices and Other Considerations

Pfizer

## Biosimilar Implementation: An Overview

Biosimilars have layered additional complexities into the traditional evaluation process used by Pharmacy and Therapeutic (P&T) committees in considering a new product for formulary inclusion. To ensure efficient implementation, a thoughtful assessment of the strategies and tactics related to an institution's operational considerations is required.[1,2]

The considerations found in these pages may help you develop the implementation strategy that will be most effective at your institution.

P&T evaluations include several key aspects (including scientific review, financial and coverage assessment, and operations). Thoughtful considerations of these aspects will help build a thoughtful implementation strategy. Clear timelines, defined roles and responsibilities, and a careful assessment of resources will help to ensure smooth implementation strategy execution.

### Strategic Considerations for P&T Evaluation[1,2]

**Scientific Review (Product-Specific)** + **Financial and Coverage Assessment** + **Operational Considerations**

**Pharmacy-Driven Implementation Strategy**

Supported by defined timelines, roles, and responsibilities, and necessary resources for execution at a given institution

Following development of an implementation strategy, tactical execution should involve a multidisciplinary collaboration among physicians and pharmacists, as well as other medical and administrative staff.[3,4]

## Factors for P&T Consideration

### Scientific Review

Although evaluation of a biosimilar will include similar components to a conventional drug or biologic review, the P&T committee's scientific review should include factors unique to a biosimilar, such as[4]:

- Data determining the similarity to a reference biologic[1,4]
- Emphasis on molecular characterization, pharmacokinetics/pharmacodynamics, and immunogenicity assessments[1,4]
- Clinical studies demonstrating biosimilarity and no clinically meaningful differences with the reference biologic[1,5]
- Differences in approved indications for the biosimilar due to reference drug exclusivity[5]
- Changes to the delivery of the reference biologic that may differ from the approved biosimilar's dosing/administration[1,4]

### Financial and Coverage Assessment

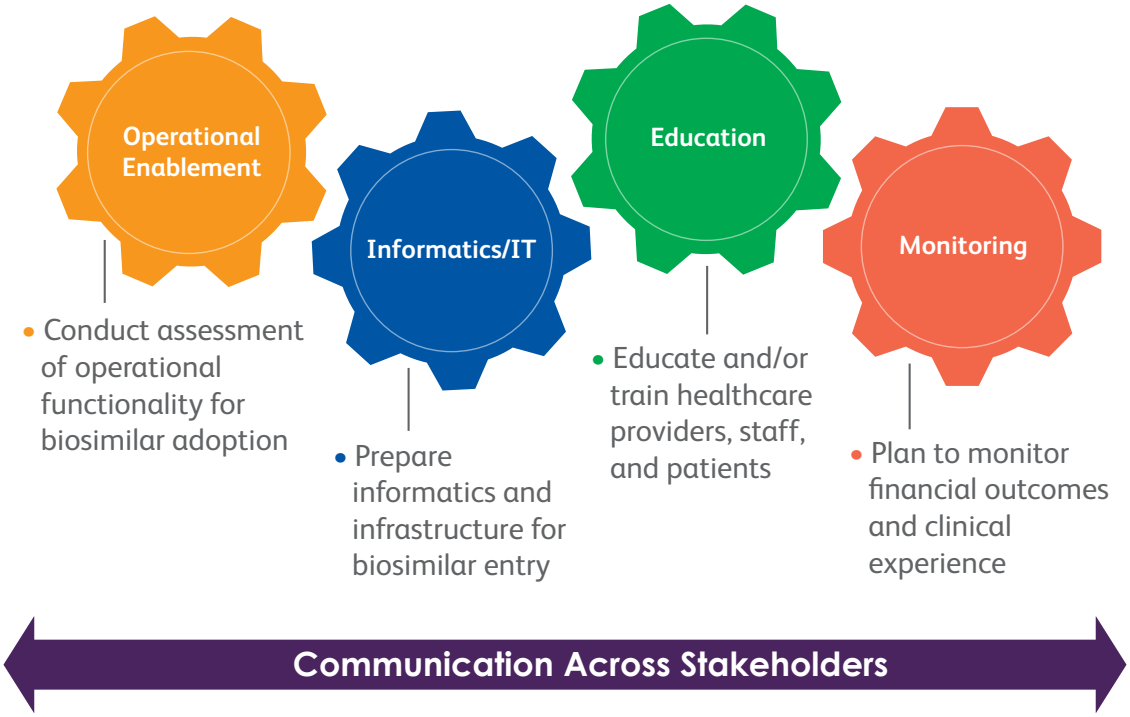
The P&T committee's financial and coverage assessment to evaluate the value of implementing a biosimilar may encompass various economic considerations, such as:

- Impact on budget[4]
- Systemwide product utilization[6]
- Payer mix and policy[2,4]
- Biosimilar landscape[7]
- Patient out-of-pocket costs[4,5]
- Billing and payment[7]

## Factors for P&T Consideration (cont'd)

### Operations

Operational considerations form four critical elements that may be included in the implementation strategy,[1,3,4,7-10] namely:




Clear communication of the biosimilar initiative and implementation strategy should be maintained across stakeholders throughout the medication-management continuum.[3]

The application of traditional formulary and practice management tools and principles, coupled with key concepts that have been identified as potential best practices for a P&T committee's evaluation of a biosimilar for formulary inclusion, may aid in the appropriate adoption, and safe and effective use, of biosimilars in clinical practice.[4]

The following pages will delve deeper into the considerations and best practices for each of the critical elements shown above. Please note that some operational considerations may not be applicable to all institutions.

# Operational Enablement

## Examples of Operational Enablement Considerations for P&T Evaluation

- **Benefits verification and payer coverage**
  - Would benefits verification be performed ***in bulk*** or ***on a rolling basis***?
  - What modifications need to be made to **workflows**? Would the changes require additional resources (eg, personnel, funds)?[7]
  - Are the benefits verification **processes integrated with electronic health record systems** to facilitate a quick order process?[10]
  - How would **prior authorization** be set up to ensure coverage?[10]
  - If formulary also includes other biosimilars or reference product, **which patients would get which drug**?[4]
  - How would **multiple biosimilars under multiple payers** be managed?
- **Patient transition plan**
  - How would the **transition** to biosimilars **be sequenced** (eg, all at once, phased in by clinic or therapeutic area, existing versus treatment-naive patients)?[2,4]
- **Procurement, inventory, and storage considerations**
  - Where would the product be **stored** and **how much** should be stocked?[1]
  - What modifications would be required **to inventory management systems** (including automated dispensing devices and software) to integrate the biosimilar and enable accurate identification?[1,4]
  - Can the manufacturer ensure a reliable and uninterrupted product supply?[1]

## Potential Best Practices for Tactical Execution of Operational Enablement Considerations

- **Verify commercial benefits**
  - Establish an updated workflow to ensure timely benefits verification[10]
  - Establish supplemental benefits verification process for biosimilar-eligible patients
  - When switching patients from reference biologic to biosimilar, verification may be performed in bulk or on a rolling basis
    - Identify eligible* patients based on payer type, medication, and imminent appointment date (for rolling basis)
    - Document prior authorization in electronic medical record[10]
  - Test the benefits verification process with a sample of patients
- **Pharmacist leads brand selection[11]**
  - Provider enters treatment plan, including drug selection[11]
  - Business office conducts benefits investigation
  - Pharmacy selects facility product of choice when multiple biosimilars are covered
    - Based on facility tier system preferences
  - Advantages include:
    - Pharmacy leads product utilization
    - Increase utilization of biosimilars
    - Pharmacy leads efforts for potential cost savings
- **Biosimilar inventory and supply should be optimized based on:**
  - Timeliness of implementation (speed of adoption) per patient transition plan established by the P&T committee[2]
  - Storage capacity (eg, refrigeration) based on institution[1,2]
    - Main depot or central supply (eg, hospitals), automated dispensing cabinetry (may be connected to wholesaler), or small group practice storage space
- **Potential steps to ensure timely delivery and consistent supply**
  - Forecast demand for the supplier based on rollout plan and alert supplier of product change (conversion of reference product to biosimilar/addition of biosimilar)[2]
  - Establish additional safety measures to avoid duplication of therapy[2]
  - Ensure manufacturer can provide consistent supply[1]
  - Establish a chain of communication for daily supply (may be integrated into inventory management systems or manual)[11]
  - Chain of communication may start with the healthcare provider when he/she updates the treatment plan in the electronic health record, which is then verified by the benefits department and communicated to the pharmacy, which then ensures timely support and delivery[11]

*Biosimilar eligibility will vary depending on the organization's biosimilar conversion goals and other factors, including payer coverage, indication, and current patient therapy.

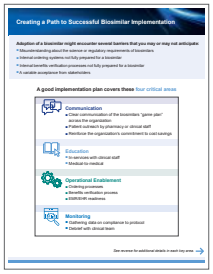
# Informatics/IT

## Examples of Informatics/IT Considerations for P&T Evaluation

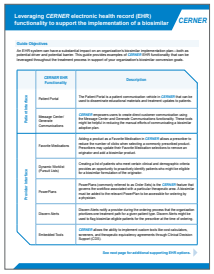
- **Systemwide Informatics/IT Infrastructure**
  - What modifications need to be made to existing order sets/care plans and protocols to include biosimilar products?[4]
  - **Plan for converting** patient orders (eg, new versus established patients, single order versus treatment plan, route for co-signature)?[1,2,4]
  - Which **electronic health record system functionality/interface** can be leveraged to support the organization's biosimilar conversion goals?[1,4]

## Pfizer has developed additional materials to help provide more specific guidance related to Informatics/IT and Biosimilar Implementation—ask your Pfizer representative to learn more.

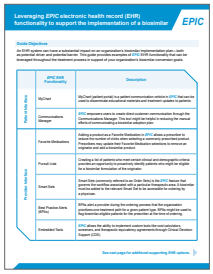
### Help With Leveraging Select EMR for Biosimilar Pull-through




Implementation Road Map



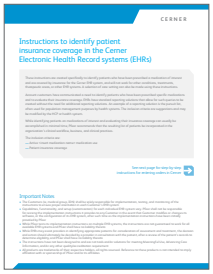

EHR Tip Sheet (CERNER)



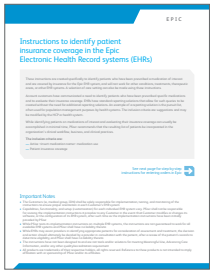

EHR Tip Sheet (EPIC)


EHR Tip Sheet (MEDITECH)

### Help With Patient Coverage Identification




EHR Brochure (CERNER)




EHR Brochure (EPIC)

## Potential Best Practices for Tactical Execution of IT Considerations

*Addition of biosimilar to the health system workflows to enable selection, accurate identification, and tracking across the medication continuum*

- **Building the backbone to enable appropriate product billing**[1,4,12]
  - Addition of Q-codes, NDC, billing units, CDM, charge methodology and consistency, waste functionality, dilution, stability, BUD to different processing systems (eg, for appropriate sterile compounding automation, ability to scan at bedside)
  - Charge master (eg, mark-up consistency, charge validation)
- **EHR/EMR (EPIC, MEDITECH, or CERNER) functionality and readiness**[1,4,12]
  - Addition of biosimilar clinical information required for users
  - Ensure ability to process the 4-attribute vocabulary of biosimilars (biosimilar brand name, biosimilar ingredient, originator brand name, originator INN)
  - Leverage the appropriate EHR functionality/interface to support the organization's biosimilar conversion goals
- **Automated dispensing system software and purchasing systems**[1,4,12]
  - Ensure ability to correctly represent biosimilar product in electronic data transfer
  - Ensure ability to differentiate biosimilar product in the eRx system
- **Update order sets or care plan workflow**
  - **Ensure availability in order sets or care plans:** Update order sets for the relevant disease states to include the biosimilar[1,4,11,12]
  - **Capability to set preference for biosimilar in order sets or care plans:** Capability to set the biosimilar as the default order for biosimilar-eligible patients[11]
  - **Facilitate biosimilar ordering through favorite medications:** Encourage relevant providers to add the biosimilar as a favorite medication to reduce the number of clicks in the ordering process[11]
  - **Update order sets or care plans to reflect new workflow:** Add new workflow step in order sets that allows providers to trigger a benefits verification for a biosimilar-eligible patient[11]
  - **Add advanced order workflow:** Include an embedded therapeutic equivalency protocol agreement that captures the prescribing physician's approval and allows a pharmacist to initiate a biosimilar switch based on preferred facility tier system and payer benefit[1,4]
- **Notifications**
  - **Provider notifications:** Identify biosimilar-eligible patients at the time of the office visit[11]
  - **Pharmacy notifications:** Alert pharmacy when the originator is ordered for a biosimilar-eligible patient[4]

BUD=beyond use date; CDM=charge description master; EHR=electronic health record; EMR=electronic medical record; eRx=electronic prescribing; INN=international nonproprietary name; IT=information technology; NDC=National Drug Code.

## Education

### Examples of Education Considerations for P&T Evaluation

- **For Internal Stakeholders**[7,10]
  - Who are the **most critical stakeholders** to target for biosimilar education?
  - **What education** will need to be provided to prepare for biosimilar adoption?
  - Does the **pharmacy team** have the **bandwidth** to fully train and educate internal stakeholders?
- **For Patients**[8,12]
  - Who will be responsible for patient education?
  - What **patient education materials** will be needed to support biosimilar use?
  - Are there **patient-appropriate materials** available that provide a **balanced outlook** (to avoid potential nocebo effect)?

## Potential Best Practices for Tactical Execution of Education Considerations

- Pharmacists can play a role in educating HCPs on biosimilars, since increased HCP knowledge of biosimilars will likely lead to increased confidence in prescribing them[4,13,14]
- Manufacturers may provide some of the necessary education materials[1]

### For Internal Stakeholders

- Organization-wide understanding is needed for the following scientific concepts[4,12,14]:
  - Biosimilar approval process and regulation
  - Key concepts on extrapolation and interchangeability designation
  - Naming and labeling
  - Any differences in REMS and the importance of pharmacovigilance
- Understanding of the administrative details below will also be required of an organization[1,4,15]:
  - Contracting terms and conditions
  - Ordering procedure
  - Reimbursement policies
  - Pharmacovigilance
  - Benefits verifications
  - Prior authorizations

### For Patients

- Education will be needed for the following[1,4,14]:
  - Patient understanding and acceptance of a biosimilar (if required by state notification/law)
  - Co-pay and insurance differences
  - Any patient assistance programs/support services by manufacturer

HCP=healthcare provider; REMS=risk evaluation and mitigation strategies.

## Monitoring

### Examples of Monitoring Considerations for P&T Evaluation[1,10]

- How would the institution ensure that **biosimilar protocol** is followed?
- How will **financial** and **drug use evaluation (DUE)** outcomes be monitored to assess if value of the biosimilar was achieved?

# Potential Best Practices for Tactical Execution of Monitoring Considerations

## For Financial Outcomes

- Provide internal analysis and updates on cost savings[4]
- Use demonstrated cost savings to leverage payer contract negotiations to improve payment and patient access [1,7]

## For DUE Outcomes[2,10]

- Experience with biosimilars
  - Debrief with clinicians to learn about the post-implementation experience with biosimilars
- Evaluate provider participation
  - Identify and connect providers who have successfully implemented biosimilars with those who may be hesitant
- Ongoing metrics
  - Gather data to inform compliance or adherence to biosimilar protocol
- Pharmacy response plan
  - Establish a clear pharmacy response when patients are prescribed originator product

## For Pharmacovigilance

- The FDA, EMA, and WHO emphasize the importance of pharmacovigilance for all biologics[16]
  - EMA and WHO recommend any pharmacovigilance plan implemented for the reference biologic to be carried over to the biosimilar
- If there is a REMS program for the reference biologic, there should also be a REMS program for the biosimilar[4,14,17]
- Established/current institutional protocols will facilitate implementation of pharmacovigilance for the biosimilar[1,4]
  - Internal tracking via bar codes and NDC
  - Electronic health records

DUE=drug use evaluation; EMA=European Medicines Agency; FDA=Food and Drug Administration; NDC=national drug code; WHO=World Health Organization; REMS=risk evaluation and mitigation strategies.

## Communication

### Examples of Communication Across Stakeholders Considerations for P&T Evaluation

- **For Internal Stakeholders**[10]
  - Who would **communicate the biosimilar adoption plan** and ensure there is good understanding of implementation strategy and tactics **across the organization**?
  - For all benefits verification options, who would be responsible for **follow-through communications** to providers?
- **For Patients**[9,10]
  - How and when would **patients be notified** of biosimilar initiatives (eg, through patient portal or direct communication; in advance of versus after benefits verification)?
  - Who would the **patients reach out** to with questions (eg, providers, pharmacies, or others)?
  - Internal tracking via bar codes and NDC
  - Electronic health records

## Potential Best Practices for Tactical Execution of Communication Across Stakeholders Considerations

- **For Prescribers**[10]
  - Inform clinicians via live meeting or email about biosimilar initiatives
  - Provide clinicians with a list of biosimilar-eligible patients
- **For Project Teams**[10]
  - Communicate implementation plan emphasizing the value of biosimilars
  - Reinforce the organization's commitment to cost savings
  - Alert provider team at point of care regarding biosimilar switch discussion with a biosimilar—eligible patient
- **For Biosimilar-Eligible Patients**[2]
  - Notify patients that their provider might discuss the possibility of switching to a biosimilar at an upcoming visit
    - Either in advance of or after proactive benefits verification
    - Via patient portal or direct communication (phone, email, etc)
  - Designate a team (eg, providers, pharmacies, or others) to answer patient queries and ensure patients are prepared

## REFERENCES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## Additional Available Resources

Please visit **PfizerBiosimilars.com** for access to the following:

- Digital tip sheets offering guidance on how to integrate a biosimilar into EPIC, CERNER and MEDITECH EHR systems
- Information about the science of biosimilars
- Downloadable resources and accessible video content for administrators, healthcare providers and patients

A speaker program providing biosimilar implementation guidance is also available—please speak with your Pfizer representative to learn more.

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