Know the Facts

An Interchangeability Designation Is Not Required for a Physician to Switch a Patient to a Biosimilar
An Interchangeability Designation Is Not Required for a Physician to Switch a Patient to a Biosimilar

The Interchangeability Designation
According to the US Food and Drug Administration (FDA), products designated interchangeable may be substituted at the pharmacy level for the reference biologic without the intervention of the prescribing health care provider.1

To be designated interchangeable1,2:

- The biological product
  - Must be biosimilar to the reference biologic
  - Must be expected to produce the same clinical result as the reference biologic in any given patient

- For a biological product administered more than once to a patient
  - The risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference biologic is not greater than the risk of using the reference biologic without such alternation or switch

An interchangeability designation considers the potential for alternation (multiple switches) between a biosimilar and reference biologic without physician intervention.1,2

<table>
<thead>
<tr>
<th>Alternation</th>
<th>Dosing Period 1</th>
<th>Dosing Period 2</th>
<th>Dosing Period 3</th>
<th>Dosing Period 4</th>
<th>Dosing Period 5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reference Biologic</td>
<td>Biosimilar</td>
<td>Reference Biologic</td>
<td>Biosimilar</td>
<td>Reference Biologic</td>
</tr>
</tbody>
</table>

As of April 2017, no biosimilar has been designated interchangeable by the FDA.

A Physician-Directed Switch

- Biosimilars are highly similar to reference biologics with no clinically meaningful differences in terms of safety, purity, and potency3
- A physician-directed switch (eg, from a reference biologic to a biosimilar) is a prescribing decision made by a patient’s physician4

Decisions to prescribe a biosimilar to patients currently stable on the reference biologic are not restricted by FDA guidance or the BPCIA2,4,5

Physician-Directed Switch

<table>
<thead>
<tr>
<th>Dosing Period 1</th>
<th>Dosing Period 2</th>
<th>Dosing Period 3</th>
<th>Dosing Period 4</th>
<th>Dosing Period 5</th>
<th>Dosing Period 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference Biologic</td>
<td>Reference Biologic</td>
<td>Reference Biologic</td>
<td>Reference Biologic</td>
<td>Reference Biologic</td>
<td>Reference Biologic</td>
</tr>
</tbody>
</table>

Physicians may prescribe a biosimilar in the same manner as they would prescribe other medications – this physician-directed decision may include prescribing a biosimilar for patients currently stable on the reference biologic (eg, single transition or switch)4


For more information, please visit PfizerBiosimilars.com