Mandated Payor Switching with Infliximab (IFX) Biosimilars

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Introduction

• The medical practice of changing one medicine for another that is expected to achieve the same clinical result in a given clinical setting and in any patient should be on the initiative of the prescriber.

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Interchangeability

- No US biosimilar agents are currently deemed interchangeable.
- Nonetheless, insurance coverage payor policies may require clinicians to interchange these agents.

Case Information

A 60-year-old white female with a history of ulcerative pancolitis was hospitalized for a deteriorating clinical course evidenced by diffuse abdominal pain and up to 6 episodes per day of bloody diarrhea. Intravenous mesalamine was given upon admission. She had been receiving mesalamine which was initially administered and then discontinued to give a first dose of IFX (Remicade®). Remicade® was formulated substituted in the hospital with infliximab-dyyb (Inflectra®) at 5 mg/kg/dose. Over the next 48 hrs, the patient had significant clinical improvement associated with resolution of her abdominal pain and rectal bleeding. On day 4, the patient was discharged to continue high dose oral prednisone and complete inflectra® induction as outpatient. The commercial insurance payor, Cigna, refused to approve the use and reimbursement of the IFX biosimilar. Repeated attempts by the provider to allow the same biosimilar that was initiated were refused and the physician's order was changed to Remicade® for continued treatment. Subsequent Remicade® infusions were generally well tolerated.

Payer Specific Criteria for Use of Infliximab and Infliximab Biosimilars

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<tr>
<th>Paper</th>
<th>Infliximab (Remicade®)</th>
<th>Biosimilar</th>
<th>Detailed Criteria for Use</th>
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<tr>
<td>Asthma</td>
<td>Allowed</td>
<td>Allowed</td>
<td>Crohn’s Disease: Patient must have failed 6-mercaptopurine/azathioprine OR corticosteroids F fistulizing Crohn’s Disease: No criteria for treatment failure; fistula must be present for at least three (3) months Ulcerative Colitis: Patient must have failed ALLContinue immunosuppression with corticosteroids for 20 days or oral therapy or 7 to 10 days for IV therapy. 5-aminosalicylic acid agents, AND immunosuppressants.</td>
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<td>Anorexia</td>
<td>Preferred</td>
<td>Allowed only upon failure or contraindication to Remicade®</td>
<td>Crohn’s Disease: Patient must have failed conventional therapy F fistulizing Crohn’s Disease: No criteria for treatment failure Ulcerative Colitis: Patient must have failed conventional therapy</td>
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<tr>
<td>Blue Cross Blue Shield of Texas</td>
<td>Allowed</td>
<td>Allowed</td>
<td>F fistulizing Crohn’s Disease: No criteria for treatment failure</td>
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<tr>
<td>Cigna</td>
<td>Preferred</td>
<td>Allowed only with intolerance to Remicade®</td>
<td>Crohn’s Disease: Patient must have failed conventional therapy F fistulizing Crohn’s Disease: No criteria for treatment failure Ulcerative Colitis: Patient must have failed conventional therapy</td>
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<td>Humana</td>
<td>Preferred</td>
<td>Allowed only upon failure with Remicade®</td>
<td>Crohn’s Disease: F fistulizing Crohn’s Disease: Ulcerative Colitis: Patient must have failed conventional therapy F fistulizing Crohn’s Disease: Ulcerative Colitis: Patient must have failed conventional therapy</td>
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<td>Scott and White Health Plan</td>
<td>Preferred</td>
<td>Allowed only with failure and intolerance to Remicade®</td>
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<td>United Healthcare</td>
<td>Preferred/Required</td>
<td>Allowed only with failure and intolerance to Remicade®</td>
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References


Discussion

• The case is an example in where a biosimilar was initiated in the hospital setting with a mandated drug switch to the reference product by the insurance payor for outpatient therapy.

• The ECCO position statement notes “Switching from originator to a biosimilar should be performed following appropriate discussion between physicians, nurses, pharmacists and patients, and according to national recommendation.”

The payer selection of biosimilars eliminates physician and patient therapy options.

• The variations noted below in payer policies for non-substantiated preferred use of originator infliximab limits the use of a lower cost biosimilar and potentially increases patient and provider costs.

• This unregulated area of payer policy merits future oversight.

Medical clinical practice must address the following with the use of biosimilars:

• Extrapolation (particularly applicable to pediatrics)
• Switching/translating
• Interchangeability

Note: Medical and pharmacy coverage policies were accessed April 30, 2018.

• The FDA evaluates each biosimilar product on a case-specific basis to determine what data are needs to demonstrate biosimilarity and which data element can be waived if deemed scientifically appropriate. This determination may be inferred by what is already publicly known about the reference product.

• Many factors can help tailor the data requirements for each biosimilar application. Some examples include:
  - Strength and robustness of the comparative analytical studies showing similar structure and function between the proposed biosimilar and the reference product.
  - Similarity of the PK and PD profiles between the biosimilar and reference product.
  - Pre-existing information about the safety profile of the reference product.
  - In April 2016 the FDA approved infliximab-dyyb (Inflectra®) as the first biosimilar agent to infliximab (Remicade®), and this was followed in April 2017 with the approval of infliximab-abbv (Remflix®).

• The Biologics Price Competition and Innovation Act (BPCIA) was established in 2009 to create an abbreviated licensure pathway for biological products that are demonstrated to be “biosimilar” or “interchangeable” with an FDA licensed biological product.¹

• Goals of the new pathway are to:
  - Reduce healthcare costs
  - Increase treatment options²

• Biosimilars are biological products that are FDA approved as being (1) “highly similar to the reference products notwithstanding minor differences in clinically inactive components” and that (2) “there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency of the product.”

• Although there are distinct approval requirements for reference products, biosimilars, and interchangeable products, the approval standards that apply to each type of biological product assure prescribers of the safety and effectiveness of each type of product. All biological products are approved only after they meet FDA's rigorous approval standards as noted in the diagram below. This leads to extrapolation with biosimilar approval for all indications of the originator product based on supporting evidence of similarity in at least 1 indication.³

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References


