The Biologics Price Competition and Innovation Act of 2009 created an approval pathway for biosimilars in the U.S. 1
To date, 21 biosimilars referencing 9 biologics have been approved in the U.S. 1
As more biosimilars are approved, accurate identification of biologics and biosimilars and understanding of use patterns and patient characteristics are fundamental needs for conducting future post-marketing studies.

To identify users of filgrastim and infliximab, the first products with biosimilars approved in the U.S. and describe their use patterns and patient characteristics.

Table 1. Biologic products included in the analysis

<table>
<thead>
<tr>
<th>Product family</th>
<th>Non-proprietary name</th>
<th>Proprietary name</th>
<th>U.S. Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>filgrastim</td>
<td>Neupogen</td>
<td>Granex</td>
<td>February 20, 1991</td>
</tr>
<tr>
<td>filgrastim-sndz</td>
<td>Zarxio</td>
<td></td>
<td>August 29, 2012</td>
</tr>
<tr>
<td>infliximab</td>
<td>Remicade</td>
<td></td>
<td>August 24, 1998</td>
</tr>
<tr>
<td>infliximab-dyb</td>
<td>Inflectra</td>
<td></td>
<td>April 5, 2016</td>
</tr>
<tr>
<td>infliximab-abd</td>
<td>Remiflex</td>
<td></td>
<td>April 21, 2017</td>
</tr>
</tbody>
</table>

Use was identified primarily via HCPCS codes (filgrastim: 86.4%-97.7%; infliximab: 87.8%-100%)
Dispensings (NDCs) identified 2.3% (filgrastim) to 13.6% (filgrastim-sndz) of filgrastim episodes and 0% (inflimab-dyb) to 12.2% (inflimab-dyb) of infliximab episodes
Among the subset of Data Partners that include NDCs in the Sentinel Common Data Model Procedure Table, 27% to 40% of filgrastim episodes and <1% to 46% of infliximab episodes had an NDC from a clinical encounter

>98% were in combination with a HCPCS code
Filgrastim reference product use declined from 89.4% in January 2015 to 30.3% in June 2016, with corresponding increases in filgrastim-sndz (0% to 43%) and tbo-filgrastim (10.6% to 20.4%) (Figure 1a)
Uptake of all infliximab biosimilars reached 9.7% in June 2018 (Figure 1b)

Patient Characteristics
Users of filgrastim products were similar in terms of age, sex, and race (Table 2)
Most filgrastim users had evidence of receiving chemotherapy for a malignancy, although the proportion with this indication was lower among filgrastim-sndz users than among users of filgrastim reference product or tbo-filgrastim
Users of an infliximab biosimilar were older and a higher proportion were of white race compared to users of infliximab reference product
A higher proportion of infliximab reference product users had evidence of a non-GI indication compared to users of infliximab-dyb and infliximab-abd, although not for users of an undetermined infliximab biosimilar

Use of biosimilar filgrastim has increased in the U.S., but uptake of infliximab biosimilars remains low
Consistent with their use in a clinical setting, use of filgrastim and infliximab was identified primarily via HCPCS codes although a substantial proportion of use was identified via NDC-based dispensings, indicating both code types should be used to identify complete exposure in future studies of these products
Patients receiving filgrastim products were largely similar, but differences in age, sex, and indication were observed across infliximab product users, suggesting the importance of confounding control in future interventional studies
Observed gaps between episodes represent patient use patterns and can inform the creation of exposure episodes in drug safety studies of biosimilars


References
1. Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, Food and Drug Administration, Silver Spring, MD
2. Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, MA