

## INDEX OF APPROVED BIOSIMILARS

The Biologics Prescribers Collaborative appreciates FDA's careful deliberation before approving biosimilar applicants. As of January 2019, there are 17 approved biosimilars, with additional approvals expected. For further information, please reference the Purple Book on FDA's site.

Biosimilar Product (Proprietary Name)	FDA Approval Date	U.S. Launch Date	FDA Approved Indications
<b>filgrastim-sndz</b> Biosimilar: Zarxio (Sandoz)  Reference biologic: Neupogen (Amgen)	March 2015	September 2015	<ul style="list-style-type: none"> <li>Patients with cancer receiving myelosuppressive chemotherapy</li> <li>Patients with acute myeloid leukemia receiving induction or consolidation chemotherapy</li> <li>Patients with cancer undergoing bone marrow transplantation</li> <li>Patients undergoing autologous peripheral blood progenitor cell collection and therapy</li> <li>Patients with severe chronic neutropenia</li> </ul>
<b>infliximab-dyyb</b> Biosimilar: Inflectra (Celltrion)  Reference biologic: Remicade (Janssen)	April 2016	November 2016	<ul style="list-style-type: none"> <li>Adult patients and pediatric patients (ages six years and older) with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy</li> <li>Adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy</li> <li>Patients with moderately to severely active rheumatoid arthritis in combination with methotrexate</li> <li>Patients with active ankylosing spondylitis (arthritis of the spine)</li> <li>Patients with active psoriatic arthritis</li> <li>Adult patients with chronic severe plaque psoriasis</li> </ul>
<b>etanercept-szsz</b> Biosimilar: Erelzi (Sandoz)  Reference biologic: Enbrel (Amgen)	August 2016	TBD	<ul style="list-style-type: none"> <li>Moderate to severe rheumatoid arthritis, either as a standalone therapy or in combination with methotrexate (MTX)</li> <li>Moderate to severe polyarticular juvenile idiopathic arthritis in patients ages two and older</li> <li>Active psoriatic arthritis, including use in combination with MTX in psoriatic arthritis patients who do not respond adequately to MTX alone</li> <li>Active ankylosing spondylitis (an arthritis that affects the spine)</li> <li>Chronic moderate to severe plaque psoriasis in adult patients (18 years or older) who are candidates for systemic therapy or phototherapy</li> </ul>
<b>adalimumab-atto</b> Biosimilar: Amjevita (Amgen)  Reference biologic: Humira (AbbVie)	November 2016	TBD	<ul style="list-style-type: none"> <li>Moderately to severely active rheumatoid arthritis</li> <li>Active psoriatic arthritis</li> <li>Active ankylosing spondylitis (an arthritis that affects the spine)</li> <li>Moderately to severely active Crohn's disease</li> <li>Moderately to severely active ulcerative colitis</li> <li>Moderate to severe plaque psoriasis</li> </ul>
<b>infliximab-abda</b> Biosimilar: Renflexis (Samsung Bioepis / Merck)  Reference biologic: Remicade (Janssen)	April 2017	July 2017	<ul style="list-style-type: none"> <li>Who have had an inadequate response to conventional therapy</li> <li>Adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy</li> <li>Patients with moderately to severely active rheumatoid arthritis in combination with methotrexate</li> <li>Patients with active ankylosing spondylitis (arthritis of the spine)</li> <li>Patients with active psoriatic arthritis</li> <li>Adult patients with chronic severe plaque psoriasis</li> </ul>

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<p>adalimumab-adbm</p> <p><b>Biosimilar:</b> Cyltezo (Boehringer Ingelheim)</p> <p><b>Reference biologic:</b> Humira (AbbVie)</p>	August 2017	TBD	<ul style="list-style-type: none"> <li>Adult patients with moderately to severely active rheumatoid arthritis</li> <li>Moderately to severely active polyarticular juvenile idiopathic arthritis in patients 4 years of age and older</li> <li>Adult patients with active psoriatic arthritis</li> <li>Adult patients with active ankylosing spondylitis</li> <li>Adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy</li> <li>Adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine or 6-mercaptopurine</li> <li>Adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy</li> </ul>
<p>bevacizumab-awwb</p> <p><b>Biosimilar:</b> Mvasi (Amgen/Allergan)</p> <p><b>Reference biologic:</b> Avastin (Genentech)</p>	September 2017	TBD	<ul style="list-style-type: none"> <li>Patients with metastatic carcinoma of the colon or rectum in combination with intravenous 5-fluorouracil-based chemotherapy</li> <li>Patients with metastatic colorectal cancer who have progressed on a first-line bevacizumab product-containing regimen</li> <li>First-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer in combination with carboplatin and paclitaxel</li> <li>Treatment of glioblastoma with progressive disease in adult patients following prior therapy as a single agent</li> <li>Treatment of metastatic renal cell carcinoma in combination with interferon alfa</li> <li>Treatment of persistent, recurrent, or metastatic carcinoma of the cervix in combination with paclitaxel and cisplatin or paclitaxel and topotecan</li> </ul>
<p>trastuzumab-dkst</p> <p><b>Biosimilar:</b> Ogivri (Mylan/Biocon)</p> <p><b>Reference biologic:</b> Herceptin (Roche)</p>	December 2017	TBD	<ul style="list-style-type: none"> <li>Adjuvant treatment of HER2-overexpressing node positive or node negative (EP/PR negative or with one high risk feature) breast cancer</li> <li>As a single agent or in combination with paclitaxel for HER2-overexpressing metastatic breast cancer</li> <li>In combination with cisplatin and capecitabine or 5-fluorouracil for the treatment of patients with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease</li> </ul>
<p>infliximab-qbtx</p> <p><b>Biosimilar:</b> Ixifi (Pfizer)</p> <p><b>Reference biologic:</b> Remicade (Johnson &amp; Johnson)</p>	December 2017	TBD	<ul style="list-style-type: none"> <li>Adult patients and pediatric patients (6 years of age and older) with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy</li> <li>Adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy</li> <li>Patients with moderately to severely active rheumatoid arthritis in combination with methotrexate</li> <li>Patients with active ankylosing spondylitis (arthritis of the spine)</li> <li>Patients with active psoriatic arthritis</li> <li>Adult patients with chronic severe plaque psoriasis</li> </ul>

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<p>epoetin alfa-epbx</p> <p><b>Biosimilar:</b> Retacrit (Pfizer/Hospira)</p> <p><b>Reference biologic:</b> Epogen/Procrit (Amgen)</p>	May 2018	November 2018	<p>Treatment of anemia due to:</p> <ul style="list-style-type: none"> <li>Chronic Kidney Disease (CKD) in patients on dialysis and not on dialysis</li> <li>Zidovudine in patients with HIV-infection</li> <li>The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of unplanned chemotherapy</li> <li>Reduction of allogeneic RBC transfusions in patients undergoing elective, noncardiac, nonvascular surgery</li> </ul>
<p>pegfilgrastim-jmdb</p> <p><b>Biosimilar:</b> Fulphila (Mylan/Biocon)</p> <p><b>Reference biologic:</b> Neulasta (Amgen)</p>	June 2018	July 2018	<ul style="list-style-type: none"> <li>Patients with cancer receiving myelosuppressive hemotherapy to decrease the incidence of infection, as manifested by febrile neutropenia</li> <li>Patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia</li> </ul>
<p>filgrastim-aafi</p> <p><b>Biosimilar:</b> Nivestym (Pfizer)</p> <p><b>Reference biologic:</b> Neupogen (Amgen)</p>	July 2018	October 2018	<ul style="list-style-type: none"> <li>Patients with cancer receiving myelosuppressive chemotherapy or induction and/or consolidation chemotherapy for AML</li> <li>Patients with cancer undergoing bone marrow transplantation</li> <li>Patients undergoing autologous peripheral blood progenitor cell collection and therapy</li> <li>Patients with congenital neutropenia</li> <li>Patients with cyclic or idiopathic neutropenia</li> </ul>
<p>adalimumab-adaz</p> <p><b>Biosimilar:</b> Hyrimoz (Sandoz)</p> <p><b>Reference biologic:</b> Humira (AbbVie)</p>	October 2018	TBD	<ul style="list-style-type: none"> <li>Adult patients with rheumatoid arthritis</li> <li>Pediatric patients (4 years of age and older) with juvenile idiopathic arthritis</li> <li>Adult patients with psoriatic arthritis</li> <li>Adult patients with ankylosing spondylitis</li> <li>Adult patients with adult Crohn's disease</li> <li>Adult patients with moderately to severely active ulcerative colitis</li> <li>Adult patients with moderate to severe chronic plaque psoriasis</li> </ul>

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<p>pegfilgrastim-cbqv</p> <p>Biosimilar: Udenyca (Coherus Biosciences)</p> <p>Reference biologic: Neulasta (Amgen)</p>	November 2018	January 2019	<ul style="list-style-type: none"> <li>Patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia to decrease the incidence of infection, as manifested by febrile neutropenia</li> </ul>
<p>rituximab-abbs</p> <p>Biosimilar: Truxima (Celltrion/Teva)</p> <p>Reference biologic: Rituxan (Roche)</p>	November 2018	TBD	<ul style="list-style-type: none"> <li>Adult patients with relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent</li> <li>Adult patients with previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy</li> <li>Adult patients with non-progressing (including stable disease), low-grade, CD20 positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine and prednisone (CVP) chemotherapy</li> </ul>
<p>trastuzumab-pkrb</p> <p>Biosimilar: Herzuma (Celltrion/Teva)</p> <p>Reference biologic: Herceptin (Roche)</p>	December 2018	TBD	<p>Adjuvant Breast Cancer of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer:</p> <ul style="list-style-type: none"> <li>As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel</li> <li>As part of a treatment regimen with docetaxel and carboplatin</li> </ul> <p>Metastatic Breast Cancer:</p> <ul style="list-style-type: none"> <li>In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer</li> <li>As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease</li> </ul>
<p>trastuzumab-dttb</p> <p>Biosimilar: Ontruzant (Samsung Bioepis)</p> <p>Reference biologic: Herceptin (Roche)</p>	January 2019	TBD	<p>Adjuvant Breast Cancer of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer:</p> <ul style="list-style-type: none"> <li>As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel</li> <li>As part of a treatment regimen with docetaxel and carboplatin</li> </ul> <p>Metastatic Breast Cancer:</p> <ul style="list-style-type: none"> <li>In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer</li> <li>As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease</li> </ul>