U.S. Real-World Biosimilar Adoption by Specialty Therapeutic Area

Poster Code: HSD49
Abstract ID: 139071

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Abstract

Objectives
Understanding trends in biosimilar adoption by specialty may advance provider and patient education while optimizing cost savings and health outcomes. Previous evaluations focused on surveys of specialty providers; however, we sought to evaluate utilization of reference versus biosimilar products by specialty across the U.S. over five years (2019-2023).

Methods
We analyzed data from Trisus Medication Compare (The Craneware Group, Edinburgh, UK) between 1/1/2019-12/25/2023 to identify encounters in eleven specialties (dermatology, endocrinology, gastroenterology, hematology, infectious diseases, nephrology, neurology, oncology, ophthalmology, rheumatology, and solid organ transplant) with a reference or biosimilar product dispensation for filgrastim, pegfilgrastim, infliximab, rituximab, bevacizumab, trastuzumab, insulin glargine, epoetin alfa, and ranibizumab. Analyses included yearly use trends overall and by specialty, age, and state.

Results
Dispensations from 1,782,569 patient encounters (reference, n=1,256,156; biosimilar, n=526,413) were included. Endocrinology (n=657,599), oncology (n=591,777), and gastroenterology (n=191,596) were most frequent; ophthalmology (n=1,824) and transplant (n=1,550) were infrequent. Biosimilar use was higher in non-academic centers (61.2% vs 55.7% with reference, p=0.0001) and outpatient settings (71.5% v. 52.1% with reference, p=0.0001). Biosimilar use was lower for pediatrics based on included indications (reference: 4.1%, biosimilar: 2.6%; p=0.0001), consistent across specialties. Biosimilar use increased annually overall (2019: 15.9%; 2020: 22.2%; 2021: 33.3%; 2022: 38.4%; 2023: 41.0%) and by specialty, except ophthalmology. Epoetin alfa use drove infectious diseases (76.5%), nephrology (62.4%), and hematology (55.4%) to have the highest biosimilar adoption rates, while ophthalmology (no use) and endocrinology (5.0%) had the lowest. Oregon, Montana, South Dakota, and Michigan had the highest biosimilar adoption rates (>45%), while New Hampshire, Alabama, and Mississippi had the lowest (<15%).

Conclusion
National data show increasing biosimilar adoption across specialty therapeutic areas, except ophthalmology, over a five-year period.

Background

- Identifying trends in biosimilar use by specialty allows for targeted approaches on a health-system and population level to advance education, increase use, and optimize cost savings
- Previous evaluations based on provider surveys demonstrate higher uptake in oncology, gastroenterology, and rheumatology, with prescriber choice mainly driven by formulary status, duration on market, patient cost savings, and patient experience[1-3]

Methods

Objectives

- **Primary:** yearly use trends of reference vs biosimilar product overall and by specialty
- **Secondary**: evaluate reference vs biosimilar product use by:
  - Treatment setting: academic vs. non-academic center, urban vs. rural, inpatient vs. outpatient
  - Age (<18 years vs. ≥18 years)
  - State

Study Population

De-identified real-world dispensations of reference and biosimilar products between 1/1/2019 – 12/25/2023 using Trisus Medication Compare

Patients grouped by ICD-10 diagnosis codes to specialty area

Dermatology, Endocrinology, Gastroenterology, Hematology, Infectious Diseases, Nephrology, Neurology, Oncology, Ophthalmology, Rheumatology, Transplant / Immunology

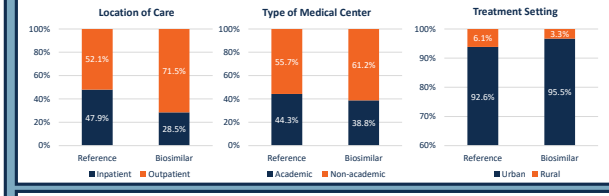
***Excluded** patients with a dispensation for both reference and biosimilar product of same drug on same encounter*

Overall study population (n=1,782,569)

Reference (n=1,256,156) | **Biosimilars** (n=526,413)

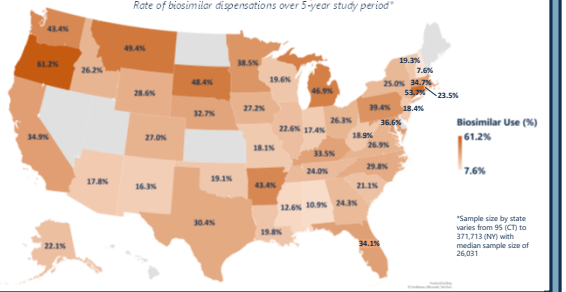
Baseline Demographics

	Reference (n=1,256,156)	Biosimilar (n=526,413)
Age, mean (years)	58.9	60.1
Age <18 years	52,112 (4.1%)	13,723 (2.6%)
Age ≥18 years	1,198,566 (95.4%)	511,595 (97.2%)
Male, n (%)	572,083 (45.4%)	231,205 (44.2%)

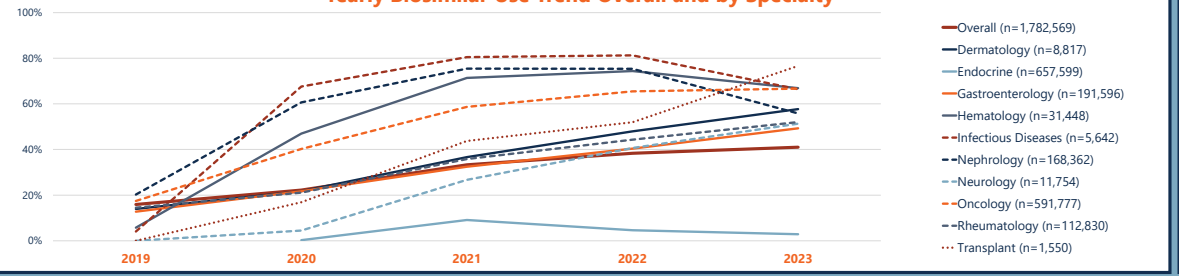


Biosimilar Use by State

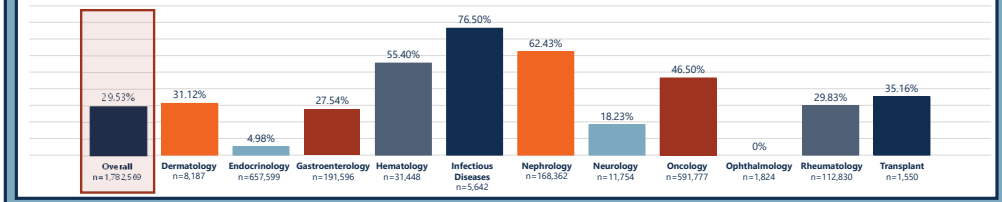
*Rate of biosimilar dispensations over 5-year study period**



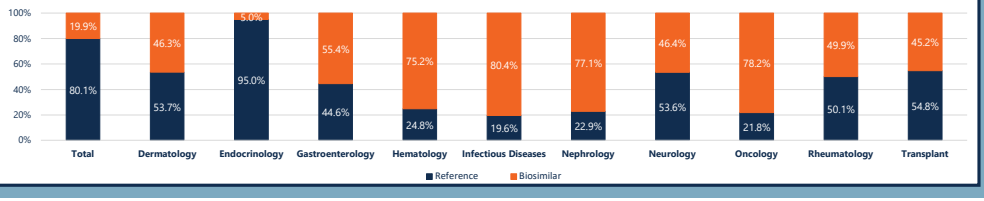
Yearly Biosimilar Use Trend Overall and by Specialty



Biosimilar Adoption Rate by Specialty



Proportion of Inpatient Dispensations of Reference vs Biosimilar Product Overall and by Specialty



Specific Product Use

Product Name	Dispensations	
FILGRASTIM	**Number**	**Percent**
Reference (Neupogen)	20,330	17.7%
Filgrastim-aafi (Nivestym)	10,595	9.2%
Filgrastim-ayow (Releuko)	0	0%
Filgrastim-sndz (Zarxio)	55,015	48.0%
Tbo-filgrastim (Granix)	28,715	25.0%
PEGFILGRASTIM		
Reference (Neulasta)	117,610	76.8%
Pegfilgrastim-fpgk (Stimufend)	0	0%
Pegfilgrastim-pbbk (Fylnetra)	0	0%
Pegfilgrastim-apgf (Nyvepria)	278	0.2%
Pegfilgrastim-bmez (Ziextenzo)	4,242	2.8%
Pegfilgrastim-cbqv (Udenyca)	25,925	16.9%
Pegfilgrastim-jmdb (Fulphila)	5,049	3.3%
INFLIXIMAB		
Reference (Remicade)	182,797	66.8%
Generic infliximab	9,852	3.6%
Infliximab-axxq (Avsola)	3,782	1.4%
Infliximab-abda (Renflexis)	28,991	10.6%
Infliximab-dyyb (Inflectra)	48,181	17.6%
RITUXIMAB		
Reference (Rituxan)	105,583	69.0%
Rituximab-arrx (Riabni)	327	0.2%
Rituximab-pvvr (Ruxience)	20,607	13.5%
Rituximab-abbs (Truxima)	26,456	17.3%
BEVACIZUMAB		
Reference (Avastin)	57,344	56.1%
Bevacizumab-awwb (Mvasi)	33,304	32.6%
Bevacizumab-bvzr (Zirabev)	11,583	11.3%
Bevacizumab-maly (Alymsys)	9	0%
Bevacizumab-adcd (Vegzelma)	0	0%
TRASTUZUMAB		
Reference (Herceptin)	59,563	59.4%
Trastuzumab-anns (Kanjinti)	25,655	25.6%
Trastuzumab-qyyp (Trazimera)	6,080	6.1%
Trastuzumab-dttb (Ontruzant)	1,146	1.1%
Trastuzumab-pkrb (Herzuma)	1,564	1.6%
Trastuzumab-dkst (Ogivri)	6,192	6.2%
INSULIN GLARGINE		
Reference (Lantus, Basaglar, Tuojeo)	624,853	95.0%
Insulin glargine-aglr (Rezvoglar)	0	0%
Insulin glargine-yfgn (Semglee)	32,746	5.0%
EPOETIN ALFA		
Reference (Epogen, Procrit)	88,090	36.3%
Epoetin alfa-epbx (Retacrit)	154,716	63.7%
RANIBIZUMAB		
Reference (Lucentis)	1,824	100%
Ranibizumab-eqrn (Cimerli)	0	0%
Ranibizumab-nuna (Byooviz)	0	0%

Discussion & Conclusions

- The rate of biosimilar use increased annually over the 5-year period
- Biosimilar adoption varied by specialty from 0% to 76.5%
  - Highest adoption specialties: infectious diseases, nephrology, and hematology
  - Lowest adoption specialties: ophthalmology and endocrinology
- Biosimilar adoption across states varied from 7.6% to 61.2%
  - Highest adoption rates: Oregon, Montana, South Dakota, and Michigan
  - Lowest adoption rates: New Hampshire, Alabama, Mississippi
- Increasing biosimilar use in inpatient setting may present cost-savings opportunity
- Limitations
  - Use of ICD-10 codes to infer use of product for specific diagnosis
  - No ability to evaluate formulary, payor, or factors affecting provider choice

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Disclosures

All authors are employees of The Craneware Group, the proprietary owner of the data analytics platform utilized in this study.

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Supplemental Information

- **Table 1:** Specialty Area with Drugs and Indications defined by ICD-10 diagnosis codes
- **Figure 1:** Demographics – Age and Treatment Setting by Specialty
- **Figure 2:** Biosimilar Adoption by State with Sample Sizes
- **Table 2:** Specific product use overall and by specialty

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Table 1: Specialty Area with Drugs and Indications defined by ICD-10 Code

Specialty Therapeutic Area	Drugs	Indications
Oncology	Bevacizumab	Cervical cancer (C53, D06) Colorectal cancer (C7A.02; C18.0; C18.2; C18.3; C18.4; C18.5; C18.6; C18.7; C18.8; C18.9; C20) Glioblastoma (C71.9) Hepatocellular carcinoma (C22.0; C22.1; C22.7; C22.8; C22.9) Non-small cell lung cancer, nonsquamous (C34) Ovarian (epithelial), fallopian tube, or primary peritoneal cancer (C56.1; C56.2; C56.3; C56.9; C57.0; C48.0; C48.1; C48.2; C48.8) Renal cell carcinoma (C64.1; C64.2; C64.9) Breast cancer, metastatic (C50) Endometrial cancer, recurrent or persistent (C54.1) Malignant pleural mesothelioma, unresectable (C45.0) Soft tissue sarcoma, angiosarcoma, metastatic or locally advanced (C49.0; C49.1; C49.2; C49.3; C49.4; C49.5; C49.6; C49.8; C49.9) Soft tissue sarcoma, hemangiopericytoma (D48.1)
	Filgrastim	Chemotherapy-induced myelosuppression in nonmyeloid malignancies (D70.1) Acute myeloid leukemia following induction or consolidation chemotherapy (C92) Bone marrow transplantation (Z94) Hematopoietic radiation injury syndrome, acute (T66.XXXA, T66.XXXD, T66.XXXS) Peripheral blood progenitor cell collection and therapy (Z52.001, Z52.011, Z52.091) Severe chronic neutropenia (D70 or D70.9) Fanconi-associated neutropenia (D61.09) Hematopoietic cell mobilization in healthy donors for peripheral blood stem cells for allogeneic transplantation (Z52.001, Z52.011, Z52.091) Hematopoietic cell mobilization prior to betibeglogene autotemcel in beta thalassemia (Z56.1) Myelodysplastic syndrome associated anemia (D46) Neutropenia in advanced HIV infection (D70.3 or D70.9) Neutropenia, hepatitis C treatment associated (D70.3 or D70.9) See link for list of codes that support medical necessity: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=57789&ver=11 and https://mcgs.bcbsfl.com/MCG?mcgId=09-J0000-62&pv=false
	Pegfilgrastim	Hematopoietic radiation injury syndrome, acute (T66.XXXA, T66.XXXD, T66.XXXS) Prevention of chemotherapy-induced neutropenia (see above in filgrastim)
	Rituximab	Chronic lymphocytic leukemia (C91.1) Other and unspecified types of non-Hodgkin lymphoma (C85) Follicular lymphoma (C82) Non-follicular lymphoma (C83, excluding C83.1 mantle cell lymphoma, C83.7 Burkitt lymphoma, C83.07 splenic marginal zone lymphoma) Burkitt lymphoma (C83.7) Graft-versus-host disease, chronic, steroid-refractory (D89.811) Hodgkin lymphoma, nodular lymphocyte-predominant, advanced (C81.4) Mucosa-associated lymphoid tissue lymphoma (gastric), advanced (C88.4) Non-Hodgkin lymphomas: Splenic marginal zone lymphoma (C83.07)
	Trastuzumab	Breast cancer (C50) Gastric cancer, metastatic (C16) Colorectal cancer, metastatic, HER2 overexpressing, with progression on conventional chemotherapy (C18) Endometrial cancer (uterine serous), advanced or recurrent, HER2-positive (C54)
	Epoetin alfa	Anemia due to chemotherapy in patients with cancer (D63.0, D64.81) Myelodysplastic syndromes (symptomatic anemia management) (D46)
Rheumatology	Infliximab	Ankylosing spondylitis (M45) Psoriatic arthritis (L40.5) Rheumatoid arthritis (M05, M06) Sarcoidosis, refractory (D86)
	Ritixumab	Wegener's granulomatosis, also known as granulomatosis with polyangiitis (M31.3) Microscopic polyangiitis (M31.7) Rheumatoid arthritis (M05) Dermatomyositis and polymyositis, refractory disease (M33) Other systemic involvement of connective tissue (M35) IgG4-related disease (D89.89) Other rheumatoid arthritis (M06) Juvenile arthritis (M08) Polyarteritis nodosa and related conditions (M30) Systemic lupus erythematosus with organ or system involvement (M32.1, except M32.14 and M32.15) Mixed cryoglobulinemia syndrome, moderate to severe disease (D89.1)
Dermatology	Infliximab	Plaque psoriasis (L40.0) Pustular psoriasis (L40.1, L40.3) Pyoderma gangrenosum (L88)
	Rituximab	Pemphigus vulgaris (L10.0) Pemphigus foliaceus, moderate to severe (L10.2) Bullous pemphigoid (L12.0) Cicatricial pemphigoid (L12.1)
Neurology	Rituximab	Multiple sclerosis (G35) Myasthenia gravis, refractory, or muscle-specific tyrosine kinase antibody-positive (G70) Other and unspecified myopathies (G72) Neuromyelitis optica, relapse prevention (G36.0) Diffuse sclerosis of central nervous system (G37.0) Concentric sclerosis [Balo] of central nervous system (G37.5) Other encephalitis and encephalomyelitis (G04.81) Other disorders of peripheral nervous system (G64)
Nephrology	Rituximab	Lupus nephritis (M32.14 and M32.15) Membranous nephropathy, primary (N07.2) Nephrotic syndrome (N04) Unspecified nephritic syndrome (N05) Glomerular disorders in diseases classified elsewhere (N08) Renal tubulo-interstitial disorders in diseases classified elsewhere (N16)
	Epoetin alfa	Anemia due to chronic kidney disease (D63.1)
Ophthalmology	Ranibizumab	Diabetic macular edema (E08.3, E09.3, E10.3, E11.3, E13.3) Diabetic retinopathy (E08.3, E09.3, E10.3, E11.3, E13.3) Macular degeneration (H35.3) Macular edema (H34.8) Myopic choroidal neovascularization (H44.2A)
Gastroenterology	Infliximab	Crohn disease (K50) Ulcerative colitis (K51) Immune-checkpoint inhibitor induced colitis (K52.1, K 52.3, K 52.89, and K52.9)
Endocrinology	Insulin glargine	Diabetes mellitus, type 1 (E10) Diabetes mellitus, type 2 (E11, E13, E08, E09) Hyperglycemia in hospitalized patients (R73)
Hematology	Epoetin alfa	Anemia due to zidovudine in HIV-infected patients (D61.1 with B20 or B97.35) Reduction of allogeneic RBC transfusion in patients undergoing elective, non-cardiac, nonvascular surgery (D63.8) RBC transfusion refusal (substitute) (D63.8 or Z53.1, or Z53.2) Congenital and hereditary thrombocytopenia purpura (D69.42) Other primary thrombocytopenia (D69.49)
	Rituximab	Thrombotic microangiopathy (M31.1) Thrombotic thrombocytopenic purpura, acquired (M31.19) Evans syndrome (D69.41) Immune thrombocytopenia (D69.3) Waldenström macroglobulinemia (C88.0) Warm autoimmune hemolytic anemia (D59.11) Cold autoimmune hemolytic anemia (D59.12) Mixed type autoimmune hemolytic anemia (D59.13)
	Bevacizumab	Hereditary hemorrhagic telangiectasia (I78.0)
Infectious Diseases	Infliximab	COVID-19, hospitalized patients (U07.1, J12.82)
	Rituximab	Gammaherpesviral mononucleosis without complication (B27.00)
	Epoetin alfa	Anemia due to zidovudine in HIV-infected patients (D61.1 with B20 or B97.35)
Transplant / Immunology	Rituximab	Antibody-mediated rejection, treatment, heart transplantation (T86.21) Antibody-mediated rejection, treatment, kidney transplantation (T86.11) Antibody-mediated rejection, treatment, lung transplantation (T86.81) Antibody-mediated rejection, treatment, pancreas transplantation (T86.89) Posttransplant lymphoproliferative disorder (D47.Z1)

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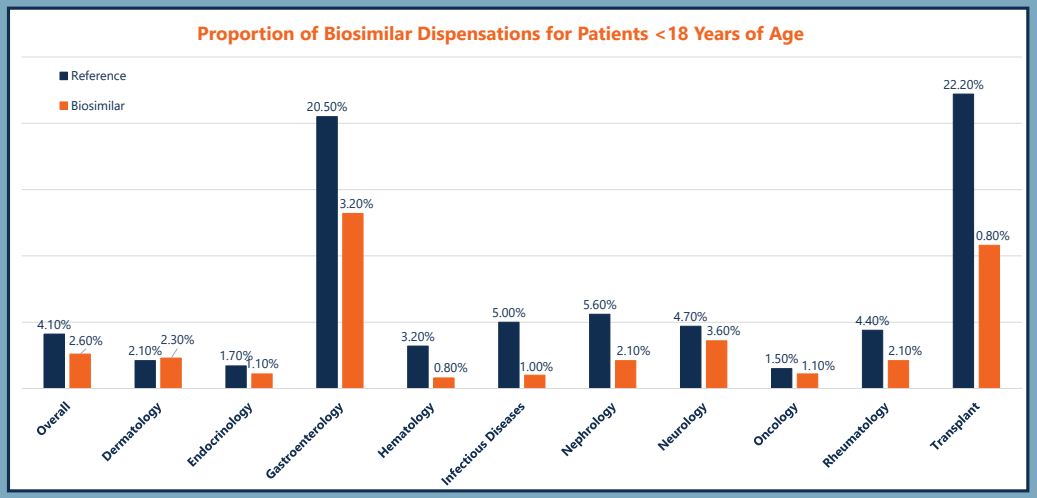
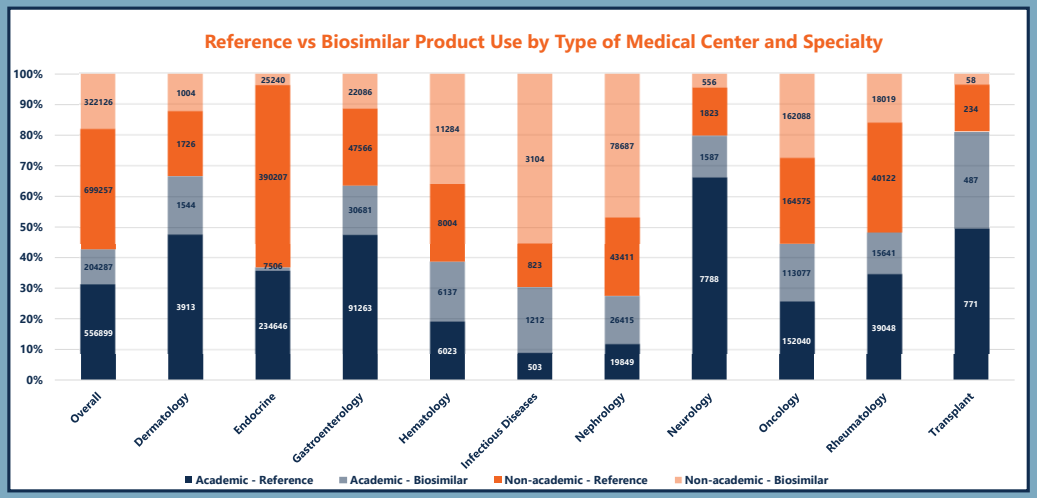
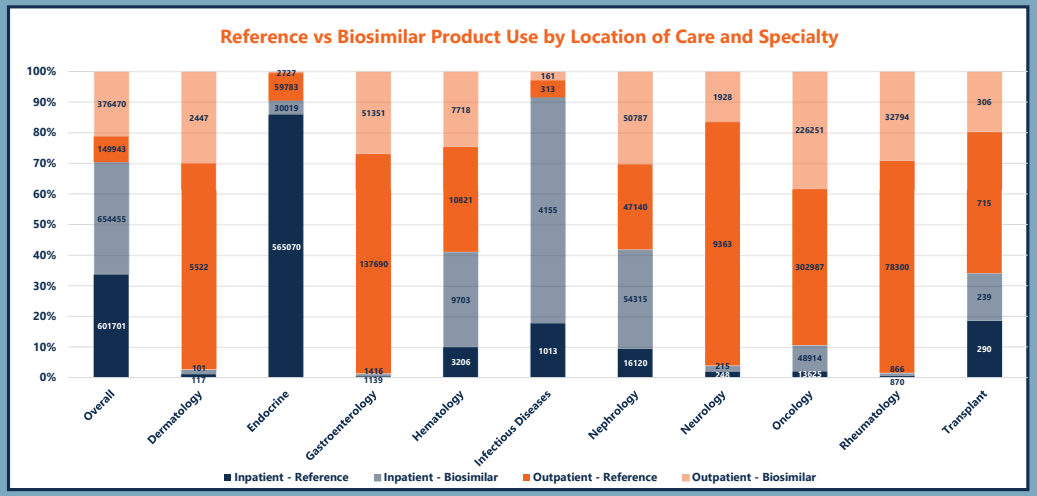
Figure 1: Treatment Setting and Age by Specialty







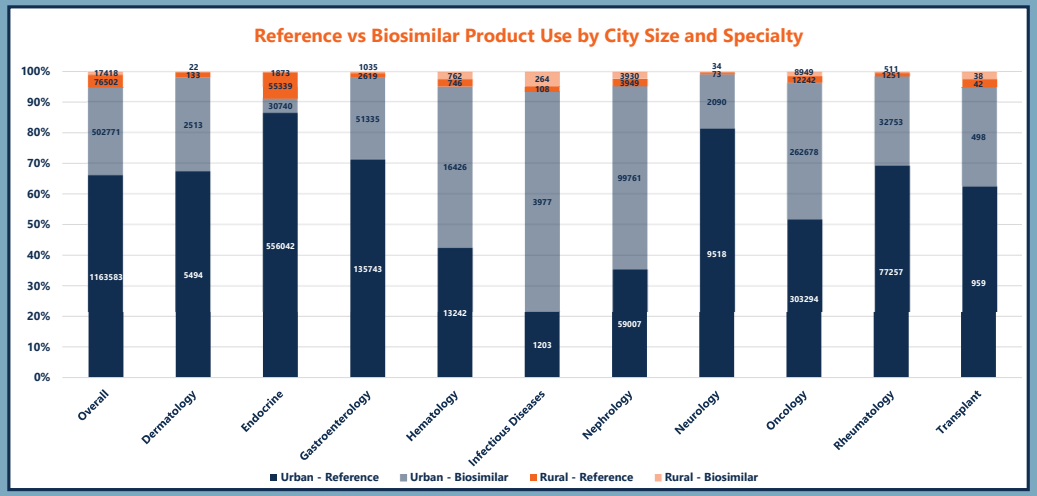


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Figure 2: Biosimilar Adoption by State with Sample Sizes

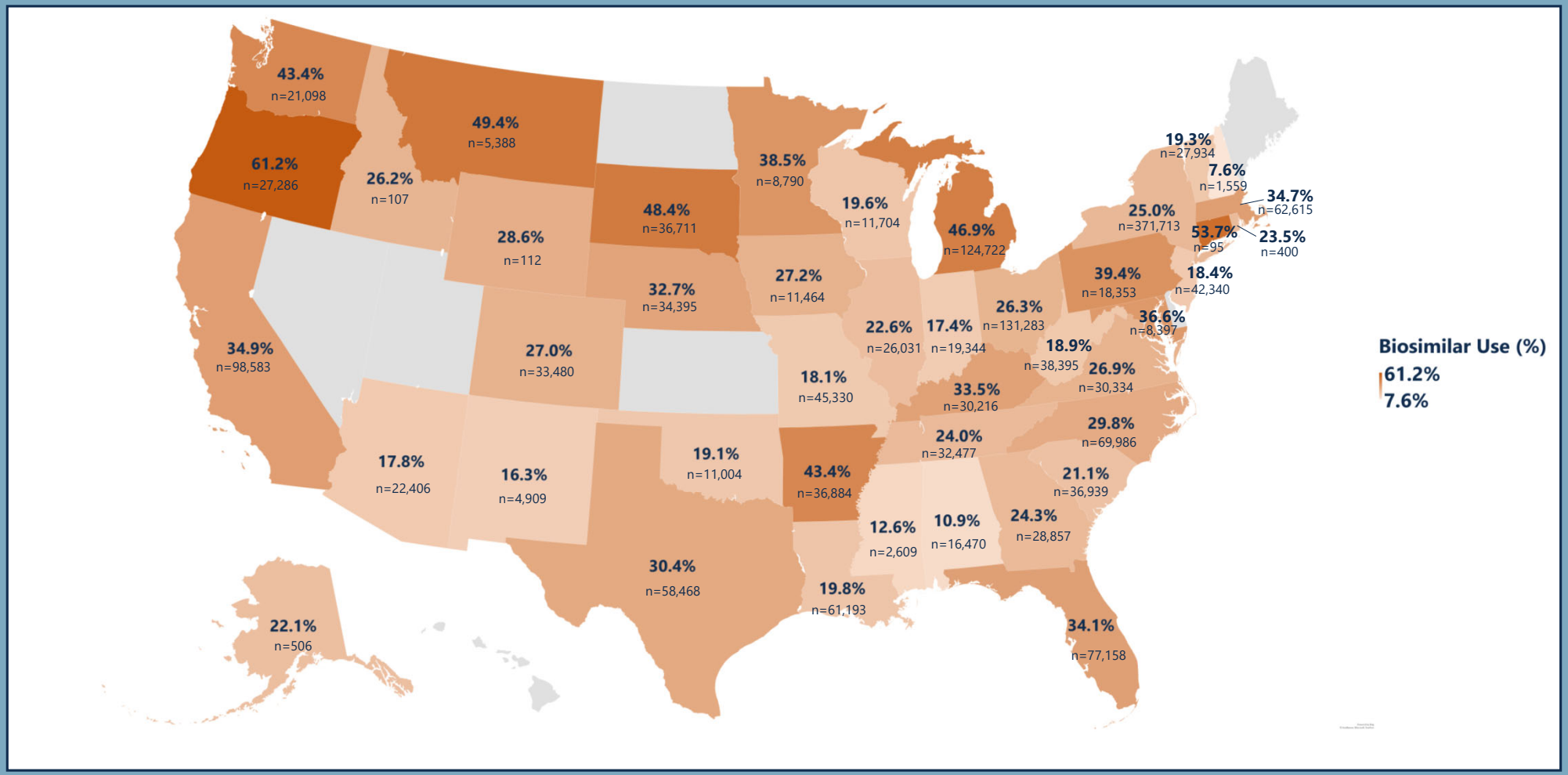

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Table 2: Specific Reference and Biosimilar Product Use by Specialty

Reference Product	Products	Overall	By Specialty										
			Dermatology	Endocrine	Gastroenterology	Hematology	Infectious Diseases	Nephrology	Neurology	Oncology	Ophthalmology	Rheumatology	Transplant
FILGRASTIM													
	Reference (Neupogen)	20330								20330			
	Filgrastim-aafi (Nivestym)	10595								10595			
	Filgrastim-ayow (Releuko)	0								0			
	Filgrastim-sndz (Zarxio)	55015								55015			
	Tbo-filgrastim (Granix)	28715								28715			
PEGFILGRASTIM													
	Reference (Neupogen)	117610								117610			
	Pegfilgrastim-fpgk (Stimufend)	0								0			
	Pegfilgrastim-pbbk (Fylnetra)	0								0			
	Pegfilgrastim-apgf (Nyvepria)	278								278			
	Pegfilgrastim-bmez (Ziextenzo)	4242								4242			
	Pegfilgrastim-cbqv (Udenyca)	25925								25925			
	Pegfilgrastim-jmdb (Fulphila)	5049								5049			
INFLIXIMAB													
	Reference (Remicade)	182797	3098		131809		30					47860	
	Generic infliximab	9852	189		7058		5					2600	
	Infliximab-axxq (Avsola)	3782	87		2382		0					1313	
	Infliximab-abda (Renflexis)	28991	710		18432		8					9841	
	Infliximab-dyyb (Inflectra)	48181	1210		31962		16					14993	
RITUXIMAB													
	Reference (Rituxan)	105583	2354			7791	325	4429	9611	51329		28739	1005
	Rituximab-arrx (Riabni)	327	3			39	2	7	12	220		41	3
	Rituximab-pvvr (Ruxience)	20607	147			2061	105	659	1066	13813		2504	252
	Rituximab-abbs (Truxima)	26456	391			2468	109	1069	1065	16093		4971	290
BEVACIZUMAB													
	Reference (Avastin)	57344				799				56545			
	Bevacizumab-awwb (Mvasi)	33304				357				32947			
	Bevacizumab-bvzr (Zirabev)	11583				154				11429			
	Bevacizumab-maly (Alymsys)	9				0				9			
	Bevacizumab-adcd (Vegzelma)	0				0				0			
TRASTUZUMAB													
	Reference (Herceptin)	59563								59563			
	Trastuzumab-anns (Kanjinti)	25655								25655			
	Trastuzumab-qyyp (Trazimera)	6080								6080			
	Trastuzumab-dttb (Ontruzant)	1146								1146			
	Trastuzumab-pkrb (Herzuma)	1564								1564			
	Trastuzumab-dkst (Ogivri)	6192								6192			
INSULIN GLARGINE													
	Reference (Lantus, Basaglar, Tuojeo)	624853		624853									
	Insulin glargine-aglr (Rezvoglar)	0		0									
	Insulin glargine-yfgn (Semglee)	32746		32746									
EPOETIN ALFA													
	Reference (Epogen, Procrit)	88090				5461	970	58896		22763			
	Epoetin alfa-epbx (Retacrit)	154716				12441	4083	103506		34686			
RANIBIZUMAB													
	Reference (Lucentis)	1824									1824		
	Ranibizumab-eqrn (Cimerli)	0									0		
	Ranibizumab-nuna (Byooviz)	0									0		