



## Utilization of anticancer biologic products among Medicare beneficiaries, by diagnostic cancer subchapter, 2006-2009

# Anticancer Biologics

## Data Points #7

The treatment of cancer has expanded considerably from surgical procedures to chemotherapy agents and radiation, and most recently, to the use of biologic products. Although the first biologic was approved in the early 1980s, the use of these agents in the treatment of cancer is still relatively new.<sup>1</sup> The type of biologic, or immunotherapeutic agent, used to treat cancer varies depending on the diagnosis.

Not all biologics are Food and Drug Administration-labeled (i.e., indicated) for the conditions in which they are used. In fact, the off-label use of cancer therapy was estimated to reach 50 to 75 percent by 2005, according to the National Comprehensive Cancer Network.<sup>2</sup> Such use is not uncommon in cancer patients who have failed more traditional treatments. The fee-for-service (FFS) Medicare program developed guidelines for medically accepted off-label use of anticancer biologics, using published drug compendia, in an effort to identify which anticancer treatments are outside the scope of Medicare coverage.<sup>3</sup> These guidelines were the result of a 1993 congressional act and have since been updated to integrate information from five various compendia providers (American Hospital Formulary Service Drug Information, DrugPoints, Clinical Pharmacology, DRUGDEX, National Comprehensive Cancer Network Drugs and Biologics Compendium).<sup>2</sup> This update was completed with input from the public and the Centers for Medicare & Medicaid Services' (CMS) Medicare Coverage Advisory Committee (MCAC).<sup>3</sup> While the off-label use of cancer therapies among the Medicare population would be expected, little is known about the distribution of diagnoses for which anticancer biologics are used.

The goal of this brief is to examine the types of cancer for which anticancer biologics are used, as identified in Medicare Parts B and D claims. The report focuses on biologics among monoclonal antibody, kinase inhibitor, biologic response modifier, other immunosuppressive and immunomodulator, and miscellaneous biologic nonblood product classes.<sup>4</sup> Information on the general utilization and cost of these biologics can be found in a companion *Data Points*.<sup>5</sup>



Fewer than 50 percent of beneficiaries with bevacizumab orders had a cancer diagnosis in the prior 6 months. This was driven by the biologic's off-label use in degenerative eye disorders.

While 83 percent of beneficiaries with erlotinib orders had a prior cancer diagnosis indicative of its use in lung cancer (a labeled indication), 69 percent had diagnoses indicative of its use in secondary malignancies and/or head and neck cancer (an off-label use).

Nearly all (98 percent) beneficiaries with *Bacillus Calmette-Guerin* (live) orders had a cancer diagnosis indicative of its use in malignant neoplasms of the genitourinary tract (e.g., bladder cancer).



## FINDINGS

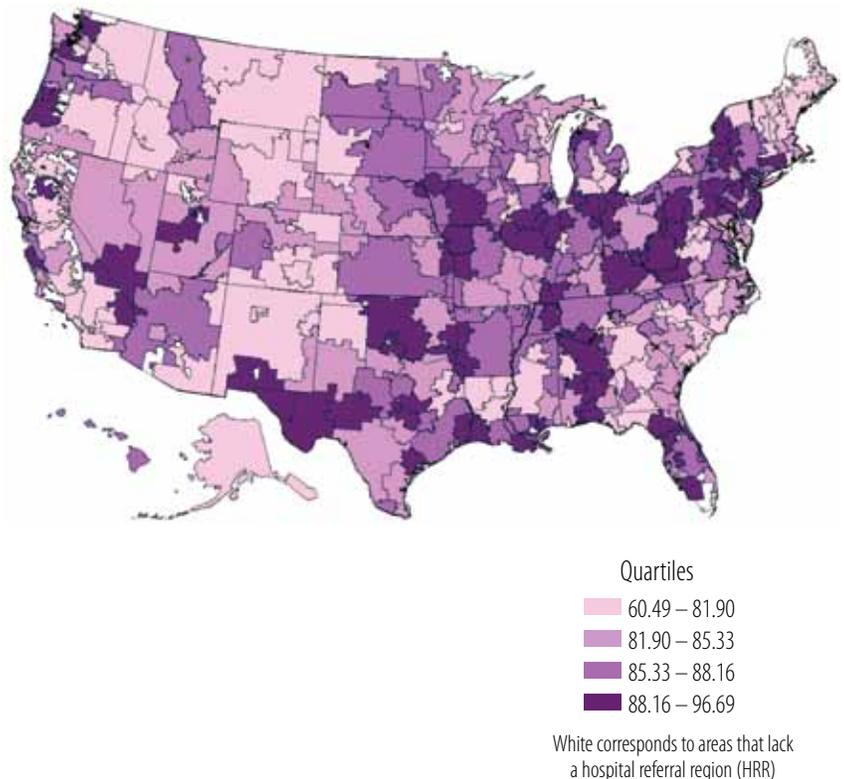
### Use of Monoclonal Antibodies by Neoplasm ICD-9 Subchapter

In the 6 months prior to the beneficiary receiving the biologic, many monoclonal antibody biologics were most frequently accompanied by an International Classification of Diseases, 9<sup>th</sup> Revision (ICD-9) diagnosis for a *hematopoietic neoplasm (200.x to 208.x)*. (Refer to the Definitions and Methods section for eligibility and time requirements for inclusion.) The biologics included: gemtuzumab (97 percent of beneficiaries had such a diagnosis in the 6 months before the order); alemtuzumab (88 percent); rituximab (84 percent); ibritumomab (70 percent); and tositumomab (44 percent).

These high proportions indicate the biologics' labeled uses in the treatment of leukemias (e.g., acute myeloid leukemia, 205) and lymphomas (e.g., non-Hodgkin's lymphoma, 202). Although the proportions of cancer diagnoses are high in these particular biologics, they do not total 100. This finding suggests the use of the aforementioned biologics in noncancer conditions such as rheumatoid arthritis (labeled and off-label), juvenile arthritis (off-label), and multiple sclerosis (off-label) is nontrivial.

In particular, rituximab, the most frequently used monoclonal antibody among Medicare beneficiaries,<sup>5</sup> is indicated in chronic lymphocytic leukemia, non-Hodgkin's lymphoma, and rheumatoid arthritis, but also used off-label for juvenile idiopathic arthritis, neuropathy/polyneuropathy, peripheral ulcerative keratitis, Waldenström macroglobulinemia, and thrombocytic purpura. While the vast majority of beneficiaries receiving rituximab had prior diagnoses of *neoplasms of lymphatic and hematopoietic tissue*, the proportion of beneficiaries with such a diagnosis varied by geography (see Figure 1).

**Figure 1:** The proportion (%) of rituximab users with a *malignancy of lymphatic and hematopoietic tissue* diagnosis in the 6 months prior, 2006-2009, by geography



Beneficiaries with orders for cetuximab and panitumumab most frequently had prior diagnoses of *malignancies of other and unspecified sites (190.x to 199.x)* and *malignancies of digestive organs and peritoneum (150.x to 159.x)*. This is indicative of the biologics' labeled use in the treatment of squamous cell carcinoma of the head and neck (cetuximab) and colorectal carcinoma (cetuximab and panitumumab). Of further interest, while bevacizumab is only labeled for use in patients with brain, breast, colorectal, kidney, and lung cancers, 54 percent of beneficiaries with an order for bevacizumab did not have a cancer diagnosis in the 6 months before their biologic claim. Further investigation determined that the vast majority of these patients had prior diagnoses for various eye conditions, indicative of bevacizumab's off-label use in the treatment of age-related macular degeneration. This practice is recommended by the American Academy of Ophthalmology Preferred Practice Pattern Guidelines.<sup>6</sup> In alignment with bevacizumab's labeled cancer indications, 24 percent of beneficiaries had a prior diagnosis of *malignancies of other and unspecified sites (190.x to 199.x)*; 16 percent *malignancies of digestive organs and peritoneum (150.x to 159.x)*; and 13 percent *malignancies of bone, connective tissue, skin and breast (170.x to 179.x)*. See Table 1 for specific diagnoses and biologics.

**Table 1:** Percentage of beneficiaries with specific cancer diagnoses, by ICD-9 subchapter, among claims for individual anticancer biologics

Anticancer Biologic	No Cancer Diagnosis ††	Malignancy of lip, oral cavity, and pharynx 140.x-149.x	Malignancy of digestive organs and peritoneum 150.x-159.x	Malignancy of respiratory and intrathoracic organs 160.x-165.x	Malignancy of bone, connective tissue, skin, breast 170.x-176.x	Malignancy of genitourinary organs 179.x-189.x	Malignancy of other and unspecified sites 190.x-199.x	Malignancy of lymphatic and hematopoietic tissue 200.x-208.x	Neuroendocrine tumors 209.x	Benign neoplasms 210.x-229.x	Carcinoma in situ 230.x-234.x	Neoplasms of uncertain behavior 235.x-238.x	Neoplasms of unspecified nature 239.x
<i>Monoclonal antibodies</i>													
alemtuzumab	6.97	0.80	5.06	4.09	16.55	3.33	11.34	87.55	†	14.53	4.75	22.89	5.24
bevacizumab	54.31	0.46	16.09	10.97	12.89	4.31	23.85	2.15	0.10	14.69	4.54	10.90	7.38
cetuximab	0.14	33.60	61.05	30.50	23.54	5.07	87.35	5.45	0.17	20.67	15.05	21.23	23.33
gemtuzumab	1.20	†	4.36	3.85	11.03	3.85	12.91	96.67	†	14.02	2.99	59.49	4.79
ibritumomab	15.84	1.43	6.91	3.85	17.86	2.47	14.85	70.40	†	18.50	4.44	19.44	8.34
panitumumab	0.27	1.17	98.26	14.76	10.03	5.30	89.08	3.22	0.37	11.35	9.73	10.19	12.36
rituximab	10.22	2.18	7.11	5.15	16.18	3.81	15.50	84.38	0.05	21.09	3.71	26.66	11.88
tositumomab	55.66	†	1.97	1.54	7.96	1.11	8.48	43.58	†	9.25	2.05	11.30	4.45
trastuzumab	88.33	0.27	1.38	1.45	10.43	0.50	9.11	1.07	†	1.73	1.94	1.77	1.85
<i>Kinase inhibitors</i>													
dasatinib	†	†	4.24	1.84	10.15	2.00	6.79	96.32	†	11.99	2.32	20.86	4.08
erlotinib	0.25	2.25	23.12	83.39	16.35	5.02	69.35	4.25	0.23	17.52	11.36	19.37	23.63
everolimus	†	†	15.34	22.49	18.25	93.12	92.59	3.97	4.23	14.81	7.94	15.61	18.78
gefitinib	†	†	3.53	94.87	13.14	†	41.03	†	†	13.78	9.29	8.65	12.82
imatinib	2.36	0.58	24.60	2.94	24.17	3.83	17.86	67.26	0.40	19.46	3.16	35.86	15.71
lapatinib	†	1.88	7.96	11.77	98.84	3.15	90.38	2.49	†	10.45	10.78	9.23	18.68
nilotinib	†	†	8.11	†	14.67	†	12.36	93.24	†	9.07	†	24.13	3.09
pazopanib	†	†	†	†	†	93.33	100.00	†	†	†	†	†	†
sorafenib	0.31	1.30	57.57	17.45	15.49	45.73	67.82	4.38	0.32	21.38	8.29	25.42	25.97
sunitinib	57.99	0.50	13.71	9.19	12.99	30.13	35.97	2.35	0.30	8.25	3.27	13.39	12.40
temsirolimus	64.75	0.67	5.34	8.70	5.66	31.92	30.97	2.85	†	5.34	2.33	5.34	6.25
<i>Biologic response modifiers</i>													
aldesleukin	6.16	2.47	14.18	16.95	46.07	39.45	66.41	11.09	†	22.34	10.17	26.50	19.11
BCG live	0.70	0.31	2.52	1.87	9.00	98.26	5.06	1.90	0.03	23.32	28.35	33.18	52.81
denileukin	0.70	0.89	4.92	3.41	24.94	2.48	5.94	97.94	†	9.46	4.16	9.24	5.34
<i>Other immunomodulators</i>													
bortezomib	0.66	0.80	3.79	3.42	18.93	3.04	31.77	98.05	0.05	15.61	3.54	24.58	7.57
interferon alfa-2b	4.24	1.10	5.90	4.44	25.35	67.44	23.96	8.99	0.25	24.82	26.20	32.69	34.06
interferon gamma-1b	67.49	†	4.95	4.64	9.13	2.32	7.74	4.95	†	13.62	3.72	10.06	4.80
lenalidomide	0.74	0.65	3.01	2.64	16.14	2.82	24.64	80.17	†	14.20	3.04	41.90	5.84
peginterferon alfa-2a	77.19	0.18	2.84	0.46	2.00	0.76	0.80	1.25	†	14.07	0.78	4.64	1.43
peginterferon alfa-2b	77.22	0.21	2.36	0.45	1.91	0.91	1.29	1.56	†	14.03	0.79	4.75	1.54
<i>Other immunosuppressive</i>													
cyclosporine	69.29	0.38	1.96	0.83	9.71	1.43	1.81	3.97	†	12.98	3.47	12.05	2.65
<i>Miscellaneous biologic nonblood products</i>													
asparaginase	9.06	†	7.09	5.91	11.81	5.91	21.65	79.92	†	16.93	†	20.87	6.30
octreotide	19.14	1.04	50.76	11.77	14.38	7.35	51.71	8.50	4.98	24.62	8.64	26.34	18.54
pegaspargase	15.44	†	10.29	8.09	15.44	8.09	22.79	58.09	†	12.50	†	25.00	8.09

† Suppressed to remain compliant with CMS' small-sized cell privacy policy

†† Includes claims with both noncancer diagnostic codes and no diagnostic code in the 6 months prior to receiving an order for a biologic

## Use of Kinase Inhibitors by Neoplasm ICD-9 Subchapter

Erlotinib, a frequently used tyrosine kinase inhibitor, was accompanied by a prior diagnosis of *malignancy of respiratory and intrathoracic organs (160.x to 165.x)* in 84 percent of beneficiaries with an order for the biologic, indicative of its labeled indication for the treatment of non-small cell lung cancer. Erlotinib is further indicated for the treatment of pancreatic cancer and has been reported to be used in patients with esophageal cancer. A diagnosis of *malignancy of digestive organs and peritoneum (150.x to 159.x)*, the code range encompassing both *malignant neoplasm of pancreas (157)* and *esophagus (150)*, appeared in 23 percent of beneficiaries with an erlotinib order.

Imatinib, another frequently used tyrosine kinase inhibitor, is indicated in *acute lymphoblastic leukemia (204.0)*, *aggressive systemic mastocytosis (202.6)*, *chronic myeloid leukemia (205.1)*, and *hypereosinophilic syndrome* and/or *chronic eosinophilic leukemia (208.1)*. Sixty-seven percent of beneficiaries with an imatinib order had a prior diagnosis of *malignant neoplasm of lymphatic and hematopoietic tissue (200.x to 208.x)*, likely driven by the biologic's use for these indications. This proportion varied by geography (see **Figure 2**). Thirty-six percent of beneficiaries had a prior diagnosis of *neoplasms of uncertain behavior (235.x to 238.x)*, indicative of its other labeled use in the treatment of *gastrointestinal stromal tumors (238.1)* and *myelodysplastic/myeloproliferative diseases (238.79)*.

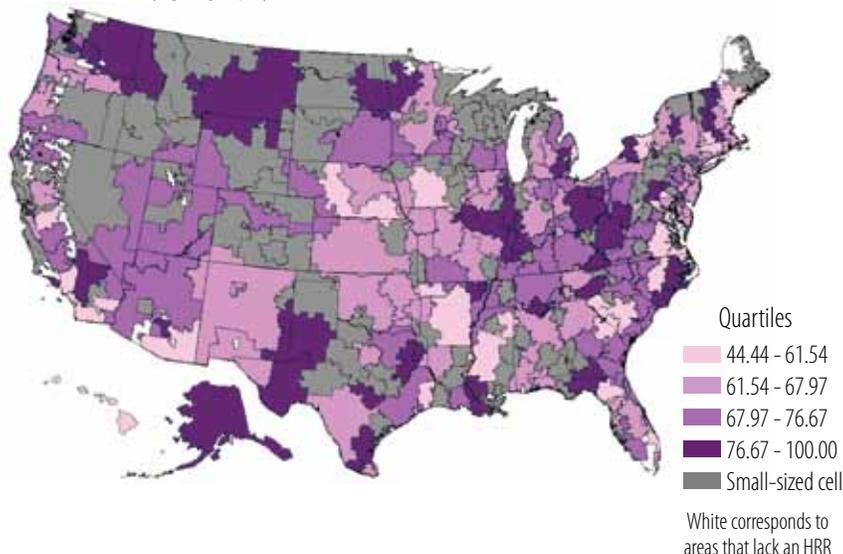
Sorafenib, a multikinase inhibitor, was used in beneficiaries with prior diagnoses arising from many cancer diagnosis subchapters, including: *malignancy of digestive organs and peritoneum (150.x to 159.x)* in 58 percent of beneficiaries; *malignancy of genitourinary organs (179.x to 189.x)* in 46 percent; *malignancy of respiratory and intrathoracic organs (160.x to 165.x)* in 17 percent; and *malignancy*

*of bone, connective tissue, skin, and breast (170.x to 176.x)* in 15 percent. These data are consistent with the biologic's indications for advanced renal cell carcinoma and hepatocellular carcinoma, and off-label use in melanoma and non-small cell lung cancer.

Everolimus and temsirolimus, mammalian targets of rapamycin inhibitors, were most often used in beneficiaries with a prior diagnosis of *malignancy of genitourinary organs (179.x to 189.x)* or *malignancy of other and unspecified sites (190.x to 199.x)*, indicative of their labeled use in advanced renal cell carcinoma and off-label use in mantle cell lymphoma. Also, nearly 16 percent of beneficiaries with an order for everolimus had a prior diagnosis of *neoplasms of uncertain behavior (235.x to 238.x)*, likely indicative of the biologic's labeled use for subependymal giant cell astrocytoma.

See **Table 1** for the proportion of beneficiaries with a particular cancer diagnosis prior to their first kinase inhibitor prescription claim.

**Figure 2:** The proportion (%) of imatinib users with a *malignancy of lymphatic and hematopoietic tissue* diagnosis in the 6 months prior, 2006-2009, by geography



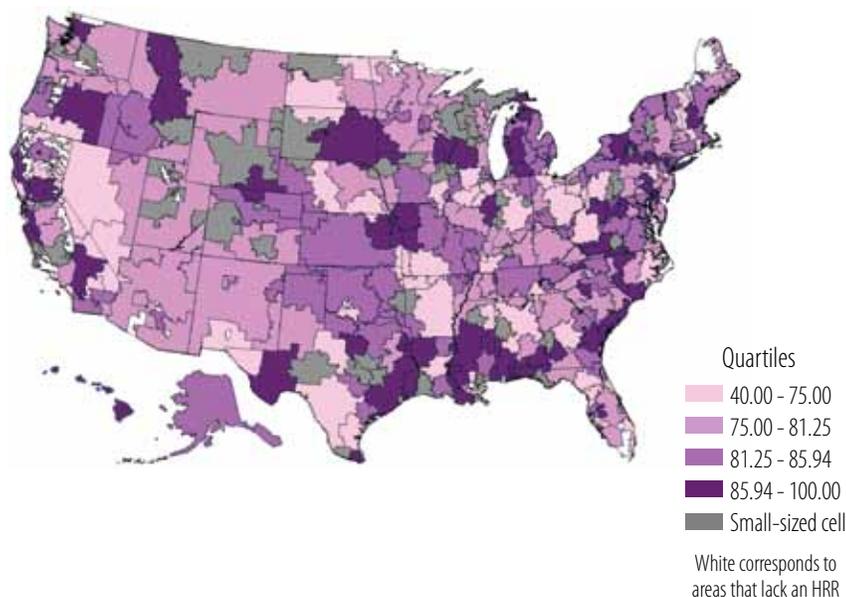
## Use of Biologic Response Modifiers by Neoplasm ICD-9 Subchapter

Bacillus Calmette-Guerin (BCG) live was accompanied by a diagnosis of *malignancy of the genitourinary organs (179.x to 189.x)* in 98 percent of beneficiaries with an order for the biologic. This high proportion is indicative of BCG live's labeled use for the treatment of bladder cancer.

Denileukin was accompanied by a prior diagnosis of *malignant neoplasm of lymphatic and hematopoietic tissue (200.x to 208.x)* in 98 percent of beneficiaries with an order for the biologic. This is indicative of denileukin's labeled use for the treatment of cutaneous T-cell lymphoma and off-label use in the treatment of non-Hodgkin's lymphoma and chronic lymphocytic leukemia.

See **Table 1** for the proportion of beneficiaries with a particular cancer diagnosis prior to their first biological response modifier prescription claim.

**Figure 3:** The proportion (%) of lenalidomide users with a *malignancy of lymphatic and hematopoietic tissue* diagnosis in the 6 months prior, 2006-2009, by geography



### Use of Other Immunomodulators, Other Immunosuppressives, and Miscellaneous Biologic Nonblood Products by Neoplasm ICD-9 Subchapter

Bortezomib (a proteasome inhibitor) and lenalidomide (an immunomodulator) each had very high proportions of beneficiaries with a prior diagnosis of *malignant neoplasm of lymphatic and hematopoietic tissue* (200.x to 208.x). This proportion varied by geography (see Figure 3 for lenalidomide). Ninety-eight percent of beneficiaries with a bortezomib order had a prior diagnosis in this subchapter, consistent with its labeled use in the treatment of *mantle cell lymphoma* (200.4) and *multiple myeloma* (203.0). Eighty percent of beneficiaries with a lenalidomide order had a prior diagnosis in the aforementioned range, consistent with its labeled use in the treatment of *multiple myeloma* (203.0). Forty-two percent of beneficiaries with a lenalidomide order had a prior diagnosis of *neoplasms of uncertain behavior* (235.x to 238.x), consistent with its labeled use for the treatment of *myelodysplastic syndromes* (238.7.x).

More than 77 percent of beneficiaries with orders for peginterferon alfa-2a or peginterferon alfa-2b had no prior cancer diagnoses. These results are consistent with peginterferon's labeled indications for hepatitis. Clearly, these biologics' off-label use in renal cell carcinoma, chronic myelogenous leukemia, and metastatic melanoma appears to be extremely limited. Similarly, 69 percent of beneficiaries with an order for cyclosporine did not have a prior cancer diagnosis. This is expected, as cyclosporine is not labeled for use in cancer, although it may be used off-label for the treatment of resistant leukemias.

See Table 1 for the proportion of beneficiaries with a particular cancer diagnosis prior to their first other immunomodulator, other immunosup-

pressive, and miscellaneous biologic nonblood product prescription claim.

Proportions of beneficiaries with a cancer ICD-9 code within 1-, 3-, and 12-month periods of continuous enrollment prior to receiving all previously discussed biologic classes appear online. Also available online are percentages of beneficiaries with a cancer Condition Category (CC) prior to receiving their first biologic claims, and alternate ICD-9 groupings.

### Utilization and Cost of Biologics

Please refer to a companion brief for detailed information on the utilization and costs of the different classes of anticancer biologics.<sup>5</sup>

### DATA SOURCE

The Department of Health and Human Services' Medicare data were used for this brief. The use of these data was covered under a project-specific data use agreement with CMS. Specifically, the Medicare Enrollment Database (EDB) was used as a source of demographic information and Medicare Parts A and B enrollment data. EDB data through April 2010 were queried. The Common Working File (CWF) was used to identify claims for biologics billed under Medicare Part B. CWF data from January 1, 2005, through April 9, 2010, were queried. Prescription Drug Event (PDE) data were used to identify Medicare Part D eligibility and biologics billed under Part D. PDE data from January 2006 through April 2010 were queried.

### STUDY PERIOD

The study period, during which biologic utilization and prior diagnoses of cancer were examined, included 2006-2009.

## ADDITIONAL FINDINGS AVAILABLE ONLINE

The following additional tables and maps appear online.

Proportion of Beneficiaries With and Without Cancer Diagnosis Prior to First Biologics Order Among Beneficiaries Satisfying a Period of Continuous AB FFS Enrollment Prior to First Relevant Claim by Class of Drug, Active Ingredient, and Period of Continuous Enrollment, 2006-2009

Cancer Condition Category (CC) With Descriptions

Proportion of Beneficiaries With and Without Cancer CC Prior to First Biologics Order Among Beneficiaries Satisfying Varying Periods of Continuous AB FFS Enrollment Prior to First Relevant Claim by Class of Drug, Active Ingredient, and Period of Continuous Enrollment, 2006-2009

Proportion of Beneficiaries With and Without Cancer CC Prior to First Biologics Order Among Beneficiaries Satisfying 6 Months of Continuous AB FFS Enrollment Prior to First Relevant Claim by Class of Drug, Active Ingredient, Age, Gender, and Race, 2006-2009

Proportion of FFS Drug Users With a 200.x-208.x Cancer Diagnosis in 6-Month Window Prior to First Fill for Rituximab, Imatinib, and Lenalidomide (separately) by HRR, 2006-2009

## DEFINITIONS AND METHODS

### Eligible Population

Eligible Beneficiaries: The population of eligible beneficiaries in a given year consists of Medicare beneficiaries continuously enrolled in Parts A and B FFS throughout the given calendar year (while alive). To identify previous cancer diagnoses, this population was restricted to beneficiaries with continuous enrollment in Parts A and B FFS throughout a given lookback period (see definition below) prior to their first biologic fill.

Four time periods of continuous enrollment were examined for this brief, and all proportions were taken over the population of beneficiaries who had at least one order for the biologic of interest, continuous FFS enrollment during the period prior to their first fill, and a diagnosis for a type of cancer in the period prior to receiving one of the biologics of interest, from 2006-2009. All results presented used a 6-month lookback period from the first biologic order of interest. Results using alternate lookback periods (1-, 3- and 12-month) are available online.

Identification of Biologics: For detailed information on the identification of biologics in Medicare, please refer to the Definition and Methods section in our companion brief.<sup>5</sup>

Identification of On-Label and Off-Label Uses for Biologics: Drug Facts and Comparisons® online resource, a comprehensive drug information compendium (online.factsandcomparisons.com) was used to identify labeled and documented off-label indications for the biologics discussed in this brief.

Identification of Cancer: Cancer diagnoses were identified using ICD-9 and CC coding systems. Results using the former are presented here, while results using the latter are available online. Geographic representations of the cancer diagnoses were limited to a high-level ICD-9 grouping category and CCs.

Lookback Period: A lookback period was defined as the number of months prior to the date of a beneficiary's first claim during which continuous enrollment in AB FFS was required. (Note: A lookback period of 6 months for a claim that occurred in February 2007 included February 2007 and spanned backward to August 2006.)

Determination of Biologic Order Counts and Proportions With Cancer Diagnoses: For each year of the study period, we: (a) used the EDB to restrict the study population to beneficiaries who were continuously enrolled in Medicare Parts A and B FFS throughout the year; (b) used the CWF to extract all Parts A and B claims containing Healthcare Common Procedure Coding System (HCPCS) or Current Procedural Terminology (CPT) codes for biologics of interest; (c) used PDE data to extract all Part D events containing National Drug Codes (NDCs) for biologics of interest; and (d) looked back 1, 3, 6, and 12 months from the date of prescription orders, restricted to beneficiaries with continuous AB FFS enrollment during the lookback period, and identified prior cancer diagnoses.

Generation of Maps: Maps were generated using Dartmouth Atlas of Health Care HRRs (www.dartmouthatlas.org). Beneficiary Zip Code of residence, as of the date of the first fill of the biologic of interest, was extracted from the EDB and crosswalked to HRRs. The proportions of beneficiaries with a cancer diagnosis of interest during the relevant lookback period, among those with exposures to a biologic of interest and continuous enrollment prior to their first fill, were grouped into quartiles and mapped accordingly. Regions with fewer than 11 beneficiaries in the numerator or denominator were mapped in gray. Geographic regions that did not correspond to an HRR were mapped in white.

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