

Corrections

Comparing the Approval and Coverage Decisions of New Oncology Drugs in the United States and Other Selected Countries. Zhang Y, Chantel Hueser H, and Hernan I. *J Manag Care Spec Pharm.* 2017 Feb;23(2):247-54.

The authors would like to make the following corrections to the above article:

- Page 247, in Abstract, replace the Results section with the following:

“Of 45 anticancer drug indications approved in the United States between January 1, 2009, and December 31, 2013, 67% (30) were approved by the European Medicines Agency, and 53% (24) were approved in Canada and Australia before December 31, 2013. The U.S. Medicare program covered all 45 drug indications, and as of June 30, 2014, the United Kingdom covered 87% (26) of those approved in Europe—58% (26) of the drug indications covered by Medicare. France, Canada, and Australia covered 42% (19), 29% (13), and 24% (11) of the drug indications covered by Medicare, respectively.”

- Page 249, replace the Results section with the following:

“Before December 31, 2013, 67% (30) of those 45 drug indications were approved by the EMA and therefore available (but possibly not covered) in the United Kingdom, and France approved all 30 EMA-approved drug indications. In Canada and Australia, 53% (24) drug indications were approved.

All these drug indications were covered by Medicare, with 23 covered in Medicare Part B and 22 covered in Medicare Part D. Figure 1 summarizes the percentage of drugs covered by Medicare that were approved and covered by other countries as of June 30, 2014, showing the total as well as stratifying by route of administration. The NHS covered 87% (26) of the 30 drugs approved in the United Kingdom, or 58% (26) of the 45 drug indications covered by Medicare. France covered 63% of the 30 drug indications approved in France, equivalent to 42% (19) of what Medicare covered, followed by Canada with 29% (13) and Australia with 24% (11) of what Medicare covered.

After stratifying by route of administration, we found that the coverage of oral anticancer drugs is less restrictive than the coverage of injections in all non-U.S. countries. Specifically, the United Kingdom covered 71% (17) of all oral anticancer drug indications in our list, but only 43% (9) of the injectable anticancer drug indications.”

- Page 252, Discussion, second paragraph, the end of second sentence, replace “47%” with “58%”; the end of last sentence, replace “31%” with “24%.”
- Page 253, Conclusions, change to the following:

“Of 45 anticancer drug indications approved in the United States between January 1, 2009, and December 31, 2013, 67% (30) were approved by the EMA, and 53% (24) were approved in Canada and Australia before December 31, 2013. As of June 30, 2014, in the United States, Medicare covered all 45 drug indications, while the United Kingdom, France, Canada, and Australia covered 58% (26), 42% (19), 29% (13), and 24% (11) of that number, respectively.”

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Corrections

- Page 250, Table 1: several corrections were made to this table. The corrected table is shown below:

TABLE 1 List of New Oncology Drugs Approved by the FDA, January 1, 2009-December 31, 2013

Brand Name	Active Ingredient	Indication	Route of Administration	Approval Dates				Coverage			
				FDA	EMA	Canada	Australia	United Kingdom	France	Canada	Australia
Abraxane	Paclitaxel protein-bound particles	Non-small cell lung cancer	Injectable	October 2012	Not Approved	Not Approved	Not Approved	NA	NA	NA	NA
Adcetris	Brentuximab vedotin	Hodgkin lymphoma and anaplastic large cell lymphoma	Injectable	August 2011	October 2012	February 2013	December 2013	Yes	Yes	Yes	No
Afinitor	Everolimus	Renal cell carcinoma	Oral	March 2009	August 2009	Not Approved	August 2009	Yes	Yes	NA	Yes
Afinitor	Everolimus	Advanced pancreatic neuroendocrine tumors	Oral	May 2011	September 2011	August 2011	July 2012	Yes	Yes	Yes	Yes
Afinitor	Everolimus	Hormone receptor-positive, HER2-negative breast cancer	Oral	July 2012	July 2012	January 2013	February 2013	Yes	Yes	Yes	Yes
Arzerra	Ofatumumab	Chronic lymphocytic leukemia	Injectable	October 2009	April 2010	August 2012	Not Approved	Yes	No	No	NA
Avastin	Bevacizumab	Renal cell carcinoma	Injectable	July 2009	January 2008	Not Approved	Not Approved	Yes	No	NA	NA
Bosulif	Bosutinib	Ph+ chronic myelogenous leukemia	Oral	September 2012	March 2013	Not Approved	Not Approved	Yes	Yes	NA	NA
Cometriq	Cabozantinib	Metastatic medullary thyroid cancer	Oral	November 2012	Not Approved	Not Approved	Not Approved	NA	NA	NA	NA
Erivedge	Vismodegib	Basal cell carcinoma	Oral	January 2012	July 2013	August 2013	May 2013	Yes	Yes	Yes	No
Erwinaze	Asparaginase Erwinia chrysanthemi	Acute lymphoblastic leukemia	Injectable	November 2011	Not Approved	Not Approved	Not Approved	NA	NA	NA	NA
Folotyn	Pralatrexate	Peripheral T-cell lymphoma	Injectable	September 2009	Not Approved	Not Approved	Not Approved	NA	NA	NA	NA
Gazyva	Obinutuzumab	Previously untreated chronic lymphocytic leukemia	Injectable	October 2013	Not Approved	Not Approved	Not Approved	NA	NA	NA	NA
Gilotrif	Afatinib	Metastatic non-small cell lung cancer with EGFR mutations	Oral	July 2013	September 2013	Not Approved	November 2013	No	Yes	NA	No
Halaven	Eribulin mesylate	Metastatic breast cancer	Injectable	November 2010	March 2011	March 2012	August 2012	Yes	Yes	Yes	No
Herceptin	Trastuzumab	Gastric cancer	Injectable	October 2010	January 2010	August 2010	September 2010	Yes	Yes	No	Yes
Iclusig	Ponatinib	Chronic myeloid leukemia and Philadelphia chromosome positive acute lymphoblastic leukemia	Oral	December 2012	July 2013	Not Approved	Not Approved	Yes	No	NA	NA
Imbruvica	Ibrutinib	Mantle cell lymphoma	Oral	November 2013	Not Approved	Not Approved	Not Approved	NA	NA	NA	NA
Inlyta	Axitinib	Advanced renal cell carcinoma	Oral	January 2012	September 2012	August 2012	July 2012	Yes	Yes	Yes	No
Istodax	Romidepsin	Cutaneous T-cell lymphoma	Injectable	November 2009	Not Approved	Not Approved	August 2013	NA	NA	NA	No
Jevtana	Cabazitaxel	Prostate cancer	Injectable	June 2010	March 2011	August 2011	December 2011	Yes	Yes	No	Yes
Kadcyla	Ado-trastuzumab	HER2-positive metastatic breast cancer	Injectable	February 2013	November 2013	October 2013	September 2013	No	Yes	Yes	No

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Corrections

TABLE 1 List of New Oncology Drugs Approved by the FDA, January 1, 2009-December 31, 2013 (continued)

Brand Name	Active Ingredient	Indication	Route of Administration	Approval Dates				Coverage			
				FDA	EMA	Canada	Australia	United Kingdom	France	Canada	Australia
Kyprolis	Carfilzomib	Multiple myeloma	Injectable	July 2012	Not Approved	Not Approved	Not Approved	NA	NA	NA	NA
Marchiqibo	Vincristine	Ph-acute lymphoblastic leukemia	Injectable	August 2012	Not Approved	Not Approved	Not Approved	NA	NA	NA	NA
Mekinist	Trametinib	Unresectable or metastatic melanoma with BRAF V600E or V600K mutations	Oral	May 2013	Not Approved	August 2013	Not Approved	NA	NA	No	NA
Perjeta	Pertuzumab	HER2+ metastatic breast cancer	Injectable	June 2012	March 2013	May 2013	May 2013	Yes	Yes	Yes	No
Pomalyst	Pomalidomide	Relapsed and refractory multiple myeloma	Oral	February 2013	August 2013	Not Approved	Not Approved	Yes	No	NA	NA
Provenge	Sipuleucel-T	Hormone refractory prostate cancer	Injectable	May 2010	September 2013	Not Approved	Not Approved	No	No	NA	NA
Revlimid	Lenalidomide	Mantle cell lymphoma	Oral	June 2013	Not Approved	Not Approved	Not Approved	NA	NA	NA	NA
Stivarga	Regorafenib	Metastatic colorectal cancer	Oral	September 2012	September 2013	April 2013	November 2013	Yes	No	No	No
Stivarga	Regorafenib	Gastrointestinal stromal tumor	Oral	February 2013	Not Approved	April 2013	Not Approved	NA	NA	No	NA
Sutent	Sunitinib	Pancreatic neuroendocrine tumors	Oral	May 2011	December 2010	Not Approved	March 2011	Yes	Yes	NA	Yes
Sylatron	Peginterferon alfa-2b	Melanoma	Injectable	April 2011	Not Approved	Not Approved	Not Approved	NA	NA	NA	NA
Synribo	Omacetaxine	Chronic or accelerated phase chronic myeloid leukemia	Injectable	October 2012	Not Approved	Not Approved	Not Approved	NA	NA	NA	NA
Tafinlar	Dabrafenib	Unresectable or metastatic melanoma with BRAF V600E mutation	Oral	May 2013	September 2013	August 2013	August 2013	No	No	No	Yes
Vandetanib	Vandetanib	Thyroid cancer	Oral	April 2011	February 2012	February 2012	January 2013	Yes	Yes	No	No
Votrient	Pazopanib	Renal cell carcinoma	Oral	October 2009	June 2010	August 2010	June 2010	Yes	No	Yes	Yes
Votrient	Pazopanib	Soft tissue sarcoma	Oral	April 2012	August 2012	August 2010	May 2011	Yes	No	No	Yes
Xalkori	Crizotinib	ALK+ non-small cell lung cancer	Oral	August 2011	October 2012	May 2012	September 2013	Yes	Yes	No	No
Xgeva	Denosumab	Giant cell tumor of bone	Injectable	June 2013	Not Approved	June 2011	Not Approved	NA	NA	No	NA
Xtandi	Enzalutamide	Metastatic castration-resistant prostate cancer	Oral	August 2012	June 2013	June 2013	Not Approved	Yes	No	Yes	NA
Yervoy	Ipilimumab	Metastatic melanoma	Injectable	March 2011	July 2011	March 2012	June 2011	Yes	No	Yes	Yes
Zaltrap	Ziv-aflibercept	Metastatic colorectal cancer	Injectable	August 2012	February 2013	Not Approved	April 2013	Yes	Yes	NA	No
Zelboraf	Vemurafenib	BRAFm+ melanoma	Oral	August 2011	February 2012	March 2012	May 2012	Yes	Yes	Yes	No
Zytiga	Abiraterone	Prostate cancer	Oral	May 2011	September 2011	July 2011	March 2012	Yes	Yes	Yes	Yes

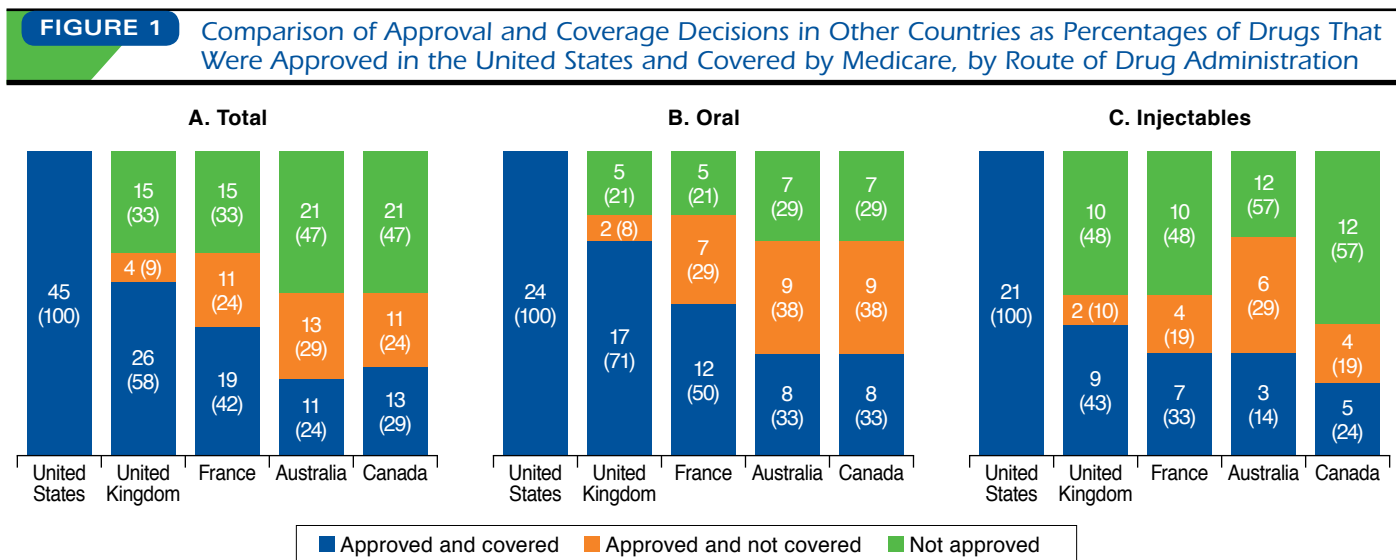
Sources: The FDA and CenterWatch websites were used to identify drugs approved by the FDA for the treatment of any cancer between the dates shown above (<http://www.fda.gov/>; <http://www.centerwatch.com/>).

Notes: The date December 31, 2013, was used as the end point for approval decisions, and June 30, 2014, was used as the end point for coverage decisions in non-U.S. countries. NA denotes not applicable because these drugs were not approved in other countries, so they were not covered.

EMA = European Medicines Agency; FDA = U.S. Food and Drug Administration.

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- Page 252, Figure 1: several corrections were made to this figure. The corrected figure is shown below:



Sources: For the United Kingdom, we reviewed the National Institute for Health and Care Excellence (<https://www.nice.org.uk/>) and the British National Formulary (<https://www.bnf.org/>) websites; for France, we reviewed the Public Database of Medications in France (<http://base-donnees-publique.medicaments.gouv.fr/index.php>); for Australia, we searched the Pharmaceutical Benefits Advisory Committee's webpage (<http://www.pbs.gov.au/info/industry/listing/participants/pbac>); and for Canada, we searched the pan-Canadian Oncology Drug Review database (<https://www.cadth.ca/pcodr>). All data were collected between March and June 2014. Further information on the algorithms used to identify coverage is available upon request.

Note: Results are expressed as n (%).