

NCHA Financial Feature



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CMS Issues Final Rule Requiring Pharmaceutical Television Advertisements to Include Pricing

The Centers for Medicare and Medicaid Services (CMS) has issued a final rule to require direct-to-consumer (DTC) television advertisements for prescription drugs and biological products for which reimbursement is available, directly or indirectly, through or under Medicare or Medicaid to include the list price of that product. The list price is being defined as prescription drugs or biological products that have a list price of more than \$35 per month for a 30-day supply or typical course of treatment. The list price is the Wholesale Acquisition Cost (WAC or list price) of that drug or biological product.

The rule has been published in the Federal Register at:
<https://www.govinfo.gov/content/pkg/FR-2019-05-10/pdf/2019-09655.pdf>.

The effective date is cited as “60 days after publication.”

The HHS Office of the Assistant Secretary for Planning and Evaluation estimates that prescription drug spending in the United States was about \$457 billion in 2015, or 16.7 percent of overall personal health care services. Of that \$457 billion, \$328 billion (71.9 percent) was for retail drugs and \$128 billion (28.1 percent) was for non-retail drugs.

CMS says that in 2017, over \$5.5 billion was spent on prescription drug advertising, including nearly \$4.2 billion on television advertising.

“The list price stated in the advertisement must be current, as determined on the first day of the quarter during which the advertisement is being aired or otherwise broadcast. When the typical course of treatment varies based on the indication for which the drug or biological product is prescribed, the list price should represent the typical course of treatment associated with the primary indication addressed in the advertisement. To the extent permissible under current laws, manufacturers are permitted to include an up-to-date list price of a competitor’s product, so long as they do so in a truthful, non-misleading way.”

The required list price disclosure must be conveyed in a legible textual statement at the end of the advertisement, meaning that it is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily.

CMS provides the following table of the 20 drugs with the highest television advertising expenditures during CY 2016. The average WAC for these drugs is \$3,473 (range: \$189 - \$16,937.91) per month.

Drug (Quantity)	WAC per Month	Representative Low Premium Plan					Representative High Premium Plan				
		Tier	Negotiated Price and Deductible	Initial Coverage	Coverage Gap	Catastrophic	Tier	Negotiated Price and Deductible	Initial Coverage	Coverage Gap	Catastrophic
Humira (2 pens)	\$5,174	Specialty	\$5,169	\$1,292	\$1,292	\$258	Specialty	\$5,097	\$1,325	\$1,274	\$255
Lyrca (60 tabs)	\$468	Preferred Brand	\$446	\$40	\$117	\$23	Preferred Brand	\$462	\$42	\$115	\$23
Xeljanz (60 tabs)	\$4,481	Specialty	\$4,477	\$1,119	\$1,119	\$224	Non-formulary	\$5,377	\$5,377	\$5,377	\$5,377
Trulicity (4 pens)	\$730	Preferred Brand	\$730	\$40	\$182	\$36	Non-preferred Drug	\$720	\$345	\$180	\$36
Xarelto (30 tabs)	\$448	Preferred Brand	\$448	\$40	\$112	\$22	Preferred Brand	\$442	\$42	\$110	\$22
Otezla (60 tabs)	\$3,398	Non-formulary	\$4,078	\$4,078	\$4,078	\$4,078	Non-formulary	\$4,078	\$4,078	\$4,078	\$4,078
Eliquis (60 tabs)	\$444	Preferred Brand	\$444	\$40	\$111	\$22	Preferred Brand	\$438	\$42	\$110	\$22
Keytruda	\$4,719	Part B									
Ibrance (30 tabs)	\$16,938	Specialty	\$17,608	\$4,402	\$4,402	\$880	Specialty	\$16,686	\$4,338	\$4,171	\$834
Jardiance (30 tabs)	\$493	Preferred Brand	\$493	\$40	\$123	\$25	Preferred Brand	\$486	\$42	\$66	\$24
Rexulti (30 tabs)	\$1,109	Specialty	\$1,109	\$277	\$277	\$55	Non-preferred Drug	\$1,093	\$525	\$273	\$55
Taltz (1 pen)	\$5,162	Non-formulary	\$6,442	\$6,442	\$6,442	\$6,442	Non-formulary	\$6,194	\$6,194	\$6,194	\$6,194
Verzenio (60 tabs)	\$12,087	Specialty	\$12,510	\$3,128	\$3,128	\$626	Non-preferred Drug	\$11,907	\$5,715	\$2,977	\$595
Prevnar-13	\$189	Part B									
Eucrisa (1 tube)	\$633	Non-formulary	\$745	\$745	\$745	\$745	Non-formulary	\$745	\$745	\$745	\$745
Latuda (30 tabs)	\$1,223	Non-preferred Drug	\$1223	\$562	\$306	\$61	Non-preferred Drug	\$1,200	\$528	\$300	\$60
Victoza (3 pens)	\$922	Preferred Brand	\$921	\$40	\$230	\$46	Preferred Brand	\$908	\$42	\$227	\$45
Farxiga (30 tabs)	\$492	Preferred Brand	\$492	\$40	\$123	\$25	Non-preferred Drug	\$486	\$233	\$121	\$24
Enbrel (4 pens)	\$5,174	Non-formulary	\$6,209	\$6,209	\$6,209	\$6,209	Specialty	\$5,097	\$1,325	\$1,274	\$255
Cosentyx (1 pen)	\$5,179	Non-formulary	\$4,661	\$4,661	\$4,661	\$4,661	Non-formulary	\$4,661	\$4,661	\$4,661	\$4,661

Our Washington liaison, Larry Goldberg of Larry Goldberg Consulting, has provided NCHA with this summary and comments. Please contact either Jeff Weegar, NCHA, at 919-677-4231, jweegar@ncha.org or Ronnie Cook, NCHA, at 919-677-4225, rcook@ncha.org if you have questions.