

JW Modifier



*Drug amount
discarded/not
administered to any
patient*

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Disclaimer Statement

I Prabath Malluwa-Wadu, CMS employee, declare no conflicts of interest or financial interests in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, or honoraria.

Outline

- Policy History
- 2017 and 2018 data
- Examples of savings with small dose vials
- From the Manual
- Limitations of JW Modifier
- Downloads

Policy History

- JW Modifier created in January 01, 2003
- Optional until January 01, 2017
 - CMS issued a CR on June 9, 2016 (Transmittal#: R3538CP)
 - MLN Matters Article #: MM9603 issued on June 10, 2016
 - CMS published a FAQ on August 26, 2016
 - Effective date adjusted to January 1, 2017 to accommodate implementation concerns from providers

Discarded Drug Units Report

- 2017

Total Allowed Amount	Total Allowed Amount for Units Administered	Total Allowed Amount for Units Discarded	Administered Units as % of Total Allowed Amount	Discarded Units as % of Total Allowed Amount
\$31,824,074,997	\$31,128,625,599	\$695,449,398	97.8%	2.2%

- 2018

Total Allowed Amount	Total Allowed Amount for Units Administered	Total Allowed Amount for Units Discarded	Administered Units as % of Total Allowed Amount	Discarded Units as % of Total Allowed Amount
\$34,756,260,823	\$34,030,984,960	\$725,275,863	97.9%	2.1%

Drug Codes with >10% Wasted

HCPCS Code	Brand Name	Generic Name	# of Vial Sizes	Weight Based Dose?	MS or SS	Single Use Vials Only?	2018 Discarded Units as % of Total Allowed Amount
J9041	Velcade	Bortezomib	1	Y	SS	Y	26.48%
J9043	Jevtana	Cabazitaxel	1	Y	SS	Y	26.24%
J9351	Hycamtin (J9351)	Topotecan HCL	1	Y	MS	Y	23.39%
J0894	Dacogen	Decitabine	1	Y	MS	Y	22.52%
J9025	Azacitidine	Azacitidine	1	Y	MS	Y	22.13%
J2796	NPlate	Romiplostim	1	Y	SS	Y	21.61%
J9017	Trisenox	Arsenic Trioxide	2	Y	MS	Y	17.81%
J9100	Cytarabine	Cytarabine	4	Y	MS	N	16.46%
J1640	Panhematin	Hemin	1	Y	SS	Y	15.90%
J0775	Xiaflex	Collagenase Clostridium Hist.	1	N	SS	Y	15.79%
J9065	Cladribine	Cladribine	1	Y	MS	Y	15.63%
J3300	Triesence	Triamcinolone Acetonide/PF	1	N	SS	Y	14.16%
J9264	Abraxane	Paclitaxel Protein-Bound	1	Y	SS	Y	13.68%
Q9950	Lumason	Sulfur Hexafluoride Microspher	1	N	SS	Y	13.12%
J1451	Fomepizole	Fomepizole	1	Y	MS	Y	12.72%
J9047	Kyprolis	Carfilzomib	3	Y	SS	Y	12.68%
J9307	Folotyn	Pralatrexate	2	Y	SS	Y	12.66%
J9178	Ellence	Epirubicin HCL	2	Y	MS	Y	12.20%
J9179	Halaven	Eribulin Mesylate	1	Y	SS	Y	11.63%
J9042	Adcetris	Brentuximab Vedotin	1	Y	SS	Y	10.61%
J9328	Temodar (J9328)	Temozolomide	1	Y	SS	Y	10.40%
J9315	Istodax	Romidepsin	1	Y	MS	Y	10.37%
J0485	Nulojix	Belatacept	1	Y	SS	Y	10.23%
J9205	Onivyde	Irinotecan Liposomal	1	Y	SS	Y	10.22%
J2562	Mozobil	Plerixafor	1	Y	SS	Y	10.21%

> 10% Wasted Drug Codes

- 19/25 one vial size
- 23/25 weight based dose
- 16/25 single source
- 24/25 single use vials only
- 19/25 in 2017 (25/25 in 2018)

2017 Top 10 Most Costly Waste

HCPCS Code	Brand Name	Generic Name	# of Vial Sizes	Weight Based Dose?	Single or Multi Source	Single Use Vials only?	Total Allowed Amount	Total Allowed Amount for Units Discarded	Discarded Units as % of Total Allowed Amount
J9041	Velcade	Bortezomib	1	Y	SS	Y	\$504,941,847.93	\$127,794,525.29	25.31%
J2796	NPlate	Romiplostim	1	Y	SS	Y	\$217,979,614.95	\$45,487,770.55	20.87%
J9271	Keytruda	Pembrolizumab	1	N	SS	Y	\$1,059,618,867.13	\$42,302,805.32	3.99%
J9264	Abraxane	Paclitaxel Protein-Bound	1	Y	SS	Y	\$277,344,459.04	\$37,884,531.39	13.66%
J9047	Kyprolis	Carfilzomib	3	Y	SS	Y	\$262,887,883.87	\$37,504,762.85	14.27%
J9035	Avastin	Bevacizumab	2	Y	SS	Y	\$1,097,318,498.44	\$34,232,714.32	3.12%
J9355	Herceptin	Trastuzumab	2	Y	SS	N	\$811,808,411.14	\$34,156,754.38	4.21%
J2357	Xolair	Omalizumab	2	Y	SS	Y	\$394,891,920.98	\$23,873,681.87	6.05%
J0585	Botox	Onabotulinumtoxina	3	Y	SS	Y	\$329,599,269.89	\$22,864,539.07	6.94%
J9025	Azacitidine	Azacitidine	1	Y	MS	Y	\$96,036,435.49	\$20,813,879.26	21.67%

Accounts for **61.4%** of total allowed amount for units discarded

2018 Top 10 Most Costly Waste

HCP Code	Brand Name	Generic Name	# of Vial Sizes	Weight Based Dose?	Single or Multi Source	Single Use Vials only?	Total Allowed Amount	Total Allowed Amount for Units Discarded	Discarded Units as % of Total Allowed Amount
J9041	Velcade	Bortezomib	1	Y	SS	Y	\$462,999,930.98	\$122,588,404.06	26.48%
J9355	Herceptin	Trastuzumab	2	Y	SS	N	\$851,399,897.40	\$77,731,188.55	9.13%
J2796	NPlate	Romiplostim	1	Y	SS	Y	\$225,939,265.97	\$48,815,556.29	21.61%
J9264	Abraxane	Paclitaxel Protein-Bound	1	Y	SS	Y	\$277,483,898.42	\$37,950,268.03	13.68%
J9047	Kyprolis	Carfilzomib	3	Y	SS	Y	\$259,705,122.69	\$32,925,500.14	12.68%
J9035	Avastin	Bevacizumab	2	Y	SS	Y	\$1,043,604,599.80	\$32,469,356.10	3.11%
J0585	Botox	Onabotulinumtoxin A	3	N	SS	Y	\$353,367,190.48	\$27,666,069.90	7.83%
J9043	Jevtana	Cabazitaxel	1	Y	SS	Y	\$100,444,301.50	\$26,358,823.67	26.24%
J2357	Xolair	Omalizumab	2	Y	SS	Y	\$411,342,516.57	\$26,037,522.19	6.33%
J1602	Simponi Aria	Golimumab	1	Y	SS	Y	\$304,266,077.97	\$23,186,626.73	7.62%

Accounts for **62.8%** of total allowed amount for units discarded

J9041

- Usual dose: 1.3 kg/m²
- Available vial size: 3.5 mg

Weight-based dose	Dose for 1.7 m ² patient	Vial size	Waste	Percent waste
1.3 mg/m ²	2.21 mg	3.5 mg	1.29 mg	36%

Patient weight/BSA to utilize entire vial:
~300kg or 2.69 m²

J9047

- Usual dose: 20—70 kg/m²
- Available vial sizes: 10 mg, 30 mg, 60 mg
- 10 mg vial became available 3Q18

Weight-based dose	Dose for 1.7 m ² patient	Possible vial size combinations	Waste	Percent waste
20 mg/m ²	34 mg	60 mg	26 mg	43.3%
		30 mg + 10 mg	6 mg	15%
27 mg/m ²	46 mg	60 mg	14 mg	23.3%
		30 mg + (2) 10 mg	4 mg	8%
56 mg/m ²	95 mg	(2) 60 mg	25 mg	20.8%
		60 mg + 30 mg + 10 mg	5 mg	5%
70 mg/m ²	119 mg	(2) 60 mg	1 mg	0.8%

From the Manual

- Medicare provides payment for the amount of drug or biological discarded as well as the dose administered, up to the amount of the drug or biological as indicated on the vial or package label
 - Medicare does not pay for overfill
 - Unused drugs or biologicals from single use vials or single use packages
 - Not multiple dose vials or packages
 - JW modifier is not permitted when the actual dose of the drug or biological administered is less than the billing unit
 - Part B drugs are not billable in fractions of HCPCS or other billing units
- Providers must record the discarded amounts of drugs and biologicals in the patient's medical record
 - Provider burden

Limitations

- The modifier is not required if no discarded drug is being billed to any payer
- Used mostly in the physician's office and hospital outpatient settings
 - drugs used incident to physicians' services
- May not be required in a hospital pharmacy
 - it may not be possible to quantify discarded quantities of drugs and associate them with a beneficiary, particularly with batch preparation
- Not required in a Rural Health Clinic (RHC) or a Federally Qualified Health Center (FQHC)
 - Drugs and biologicals are generally not separately payable under Part B
- Not intended for use under the Inpatient Prospective Payment System

Limitations

- The modifier is not required in packaged OPPS drugs
- Not used when the actual dose administered is less than the HCPCS billing unit
 - also not required if the amount of drug that is discarded is less than the amount described by one HCPCS billing unit
- Not required when the quantity of discarded drug cannot be quantified

JW Modifier is a Medicare Part B policy. CMS has no information regarding how other insurance programs are tracking/paying for wasted drugs.

Downloads

- CMS FAQ:
 - <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf>
- MLN Matters # MM9603:
 - <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9603.pdf>
- CMS CR Transmittal 3538:
 - <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3538CP.pdf>
- Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals:
 - <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf>
- Medicare Part B Discarded Drug Units Report:
 - <https://www.cms.gov/research-statistics-data-systems/cms-drug-spending/medicare-part-b-discarded-drug-units-report>

Thank you

Questions?