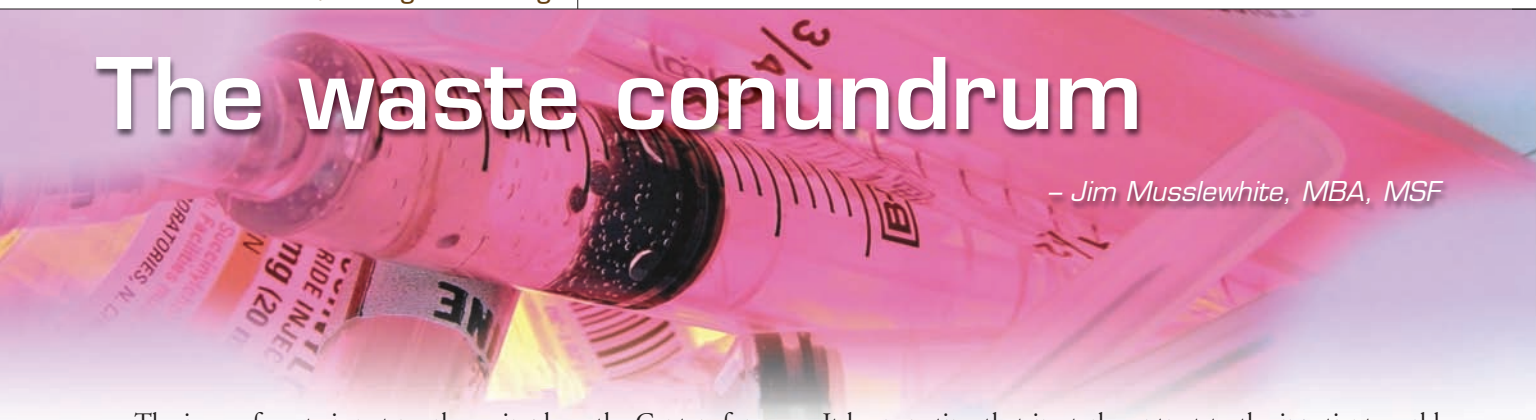
The waste conundrum



– Jim Musslewhite, MBA, MSF

The issue of waste is not nearly as simple as the Centers for Medicare & Medicaid Services' (CMS) policies would lead one to believe. In fact, the following will attempt to illustrate the various scenarios encountered in the oncology setting and the possible outcomes and inconsistencies that can occur with any waste policy that is adopted in the oncology setting. For the sake of this example, we will use only one drug to illustrate the complexity of the issue. The drug used in this example is Genentech's Avastin. The HCPCS code used to properly bill for Avastin is J9035 and the code accounts for 10mg of Avastin for every unit billed. Avastin is available in 100mg and 400mg vial sizes. Both Vial sizes are SDPF vials or single-dose preservative-free vials. Genentech's package insert states that the preservative-free vials are stable for eight hours after dilution if stored between 36-46 degrees Fahrenheit. Additionally, Genentech's dosage and administration guidelines state "Discard any unused portion left in vial, as the product contains no preservatives." It should also be noted that the possibility exists that each Avastin vial probably contains overfill. Overfill is defined as an amount sufficient to ensure that the full dose can be obtained when the bulb of a syringe is taken into account. CMS does not permit that overfill be billed due to the fact that it was not purchased.

It should also be noted that Genentech considers SDV vials to be puncture-once vials and expects the drug to be used on only one patient. I have asked for Genentech's policy on wastage, but at this time, I have not received their policy. However, their drug wastage policy can be inferred from their drug replacement policies. During the drug replacement process, documentation is provided to Genentech for the drug to be replaced. Genentech uses the medical flow sheet for documentation to indicate the amount of the drug the patient received. If the flow sheet indicates that 316mg of Avastin were administered to the patient, Genentech replaces 400mg of drug based on the fact that Avastin is a single dose vial and the remaining 90mg should be wasted. The presumption that Genentech is making is that the following occurred:

It bears noting that in stark contrast to the inpatient world where the rest of the vial is available to other patients, only 80mg out of the 84 remaining mgs would be available in a waste per day policy. Additionally, since a waste per day wastage policy (CMS's policy) is in violation of Genentech's definition of a single dose vial then, by definition, a waste per day policy will violate Genentech's drug replacement policy. Consequently, Genentech will then shut down the drug replacement process until the policy is modified because the policy creates the guarantee of overbilling on drug. As another point of reference, Genentech clearly points to the fact that Herceptin (also a Genentech drug) is a Multi-dose vial while Avastin and Rituxin are single dose vials. They state that Herceptin is stable when punctured more than once and therefore is a multi-dose vial.

Additionally, it can easily be inferred that since the dosage and administration guidelines clearly state that the remaining drug needs to be wasted, that if a vial is used for more than one patient when labeled as a single dose vial, then any malpractice claim would fall solely to the practice and not to Genentech.

As stated earlier, it should also be noted that the possibility exists that each Avastin vial probably contains overfill. CMS does not permit that overfill be billed due to the fact that it was not purchased. To properly account for overfill in a "day waste" scenario will require very detailed pharmacy dispensing rules and record keeping to ensure that the overfill is not billed to any carrier.

With the background established above, we will now review three scenarios using Avastin. Avastin is dosed by weight based on mg/kg with different dosing levels (5mg/kg to 15mg/kg) based on tumor type. We will use the same imaginary patients for each example and change the potential factors encountered to illustrate the complexity of the situation. Illustrated below are the potential pitfalls of carrying the waste to the last patient of the day. The downside is if that patient is a "no show" it creates a situation where the waste for the day may exceed the total waste created in the waste per patient scenario. Additionally,

Genentech assumption

Patient	Dose	Vial Size	Waste	J Code	Billing Units	Billing Dose	Waste Dose
XYZ	316mg	400mg	84mg	J9035	32	320	80 (JW)

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The following will attempt to illustrate the various scenarios encountered in the oncology setting and the possible outcomes and inconsistencies that can occur. Avastin is dosed by weight with different dosing based on tumor type. We will use the same imaginary patients for each example and change the potential factors encountered to illustrate the complexity of the situation. The following examples will outline different scenarios under a waste per patient and a waste per day scenario.

Example 1: Example one is what I would view as an ideal day in that all patients showed and their lab values allowed for treatment to be given.

Example 2: This example is a situation where one patient either does not show up or their vitals do not allow them to have treatment that day.

Example 3: In this example two patients are not able to have treatment with one of them being the last patient of the day. This scenario actually creates more waste than the other scenarios.

Brand Name	Generic Name	UNMH Products	ndc	Vial Size	MG/Vial	Vial	Past Usage	"Avg." Dose
Avastin ▲	Bevacizumab	Bevacizumab 25mg/mL injections	50242-0060-01	4ml	100	SDPF*	737	550mg
		Bevacizumab 25mg/mL injections	50242-0061-01	16ml	400	SDPF*	716	

(▲= Overfill potential)

*SDPF is a single dose preservative free vial

Example 1: Waste Per Patient

Patient	Show/ No Show	Dose (MG)	100MG Vial	400MG Vial	Waste (MGs)	Units w/o Waste	Units w/ Waste
ABC	Yes	282	3		18	29	30
DEF	Yes	555	2	1	45	56	60
GHI	Yes	1486	3	3	14	149	150
JKL	Yes	487	1	1	13	49	50
MNO	Yes	1241	1	3	59	125	130
PQR	Yes	283	3		17	29	30
Total	**All**	**4334**	**13**	**8**	**166**	**437**	**450**

Example 1: Waste Per Patient

Patient	Show/ No Show	Dose (MG)	100MG Vial	400MG Vial	Waste (MGs)	Units w/o Waste	Units w/ Waste
ABC	Yes	282		1	118	29	29
DEF	Yes	555		2	363	56	56
GHI	Yes	1486		3	77	149	149
JKL	Yes	487	1	1	90	49	49
MNO	Yes	1241		3	49	125	125
PQR	Yes	283	3		66	29	36
Total	**All**	**4334**	**4**	**10**	**66**	**437**	**444**

Example 2: Waste Per Patient

Patient	Show/ No Show	Dose (MG)	100MG Vial	400MG Vial	Waste (MGs)	Units w/o Waste	Units w/ Waste
ABC	Yes	282	3		18	29	30
DEF	No	0			0	0	0
GHI	Yes	1486	3	3	14	149	150
JKL	Yes	487	1	1	13	49	50
MNO	Yes	1241	1	3	59	125	130
PQR	Yes	283	3		17	29	30
Total	**All**	**3779**	**11**	**7**	**121**	**381**	**390**

Example 2: Waste Per Patient

Patient	Show/ No Show	Dose (MG)	100MG Vial	400MG Vial	Waste (MGs)	Units w/o Waste	Units w/ Waste
ABC	Yes	282		1	118	29	29
DEF	No	0			118	0	0
GHI	Yes	1486		4	232	149	149
JKL	Yes	487		1	145	49	49
MNO	Yes	1241	1	3	204	125	125
PQR	Yes	283	1		21	29	32
Total	**All**	**3779**	**2**	**9**	**21**	**381**	**384**

Example 3: Waste Per Patient

Patient	Show/ No Show	Dose (MG)	100MG Vial	400MG Vial	Waste (MGs)	Units w/o Waste	Units w/ Waste
ABC	Yes	282	3		18	29	30
DEF	No	0			0	0	0
GHI	Yes	1486	3	3	14	149	150
JKL	Yes	487	1	1	13	49	50
MNO	Yes	1241	1	3	59	125	130
PQR	No	0			0	0	0
Total	**All**	**3496**	**8**	**7**	**104**	**352**	**360**

Example 3: Waste Per Patient

Patient	Show/ No Show	Dose (MG)	100MG Vial	400MG Vial	Waste (MGs)	Units w/o Waste	Units w/ Waste
ABC	Yes	282		1	118	29	29
DEF	No	0			118	0	0
GHI	Yes	1486		4	232	149	149
JKL	Yes	487		1	145	49	49
MNO	Yes	1241	1	3	204	125	146
PQR	No	0	0		204	0	0
Total	**All**	**3496**	**1**	**9**	**204**	**352**	**373**

Medicare policies outline scenarios with a 100 percent Medicare population in the clinic. CMS has not issued guidance when patients cross insurance plans and how to handle those situations. In every example contained on the accompanying spreadsheet if the last patient is a Medicare patient, then that beneficiary (with a very significant coinsurance portion) will face a much higher payment due to other non-Medicare patient's waste. This obviously seems discriminatory and unfair to the patient, the Medicare Trust Fund, and the American taxpayer. Additionally, when the waste is billed to a Medicare patient, the practice will receive lower reimbursement for the drug waste when compared to billing the waste to a commercial insurance patient. Furthermore, the commercial insurance patient likely does not have a coinsurance portion. So you may be asking why you would not just make the last patient of the day a commercial insurance patient? The issue is that if the last patient of the day is *always* a commercial insurance patient then the Medicare patients will *never* have the possibility of incurring waste and therefore by definition they will *always* have a lower coinsurance portion at a waste per day practice compared to other oncology clinics. The lower coinsurance issue can be seen as a Stark violation for inducement for services.

The fact that the current economics of oncology mandate that all waste is captured and billed to ensure the financial viability of the clinic is not debatable. The debatable issue is a specific clinic's policy on waste. As we have stated from the beginning, there is not an easy answer to the issue of waste and a valid argument can be made for a policy that wastes by patient and a valid argument can be made for a policy that wastes at the end of the day. From a clinic process flow perspective and revenue integrity stand point the decision is easy. Fewer mistakes occur and clear double checks exist when you apply waste to each patient based on that patient's particular dose.

Jim Musslewhite, MBA, MSF, is president & CEO of, Oncology Convergence, Inc. (OCI) in Lakewood, Colo. OCI is one of the nation's only providers of oncology specific revenue management and revenue recovery consulting in the U.S., offering services to office, hospital, and integrated cancer centers with medical oncology, radiation oncology, pediatric oncology and GYN oncology practices. With offices in Denver, Kansas City, Phoenix, Tucson and Albuquerque, OCI's team has experience in the management of oncology practices, including direct experience with billing, revenue cycle management, clinical operations, IT project management, contracts negotiation. For more information go to www.oncologyconvergence.com.

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