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Dose Rounding Monoclonals Yields Windfall



National Harbor, Md.—Rounding down doses for injectable monoclonal antibodies within 10% to achieve more efficient use of vial sizes could lead to substantial savings for health plans, according to a study from Magellan Rx Management, the pharmacy benefit management division of Magellan Health Inc.

The company's review of prior authorization requests for bevacizumab (Avastin, Genentech), infliximab (Remicade, Janssen) and rituximab (Rituxan, Genentech/Biogen) among members of two regional health plans with approximately 5.6 million covered lives found that about 9% to 11% of these requests would have been eligible for dose optimization in the first quarter of 2016 alone, yielding a potential savings of more than \$2 million.



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Sam Leo, PharmD

"Certain injectables come in larger vial sizes that are meant to be split so the provider can pick their dose and keep using [the vial] until it's empty," said lead study author Sam Leo, PharmD, the director of specialty clinical programs for the company, during a poster presentation at the Academy of Managed Care Pharmacy's 2016 Nexus meeting (abstract D04). "Other products, like these, have fixed vial sizes where often you'll have to use multiple vials to get the dose that you need; and once they hit that dose, there's often waste. Whatever is left over in that vial isn't reused—it's thrown out."

Dr. Leo and his colleagues tallied prior authorization requests for bevacizumab (n=415), infliximab (n=1,028) and rituximab (n=617) received between Jan. 1 and March 31, 2016, for the two health plans, with an average approval duration of 9.2 months. They determined requests eligible for dose rounding if the calculated dose per infusion could be rounded down within 10%, as published in the *Journal of Oncology Pharmacy Practice* (2011;17[3]:246-251). Total estimated savings for both health plans for all three products was nearly \$2.17 million. Calculations were based on Average Sales Price plus 6% for Medicare patients and Average Sales Price plus 15% for commercial patients. (See Table for individual drug breakdowns.)

Drug	Eligible for Dose Rounding, %	Potential Savings Per Case, \$	Total Potential Savings, \$
Bevacizumab	9.4	9,321	363,527
Infliximab	9.7	7,600	760,018
Rituximab	11.2	15,125	1.04 million

“Prescribers will be able to use their own clinical discretion on when it’s appropriate to round the dose,” Dr. Leo said. “Even if only 30% of physicians agree to take our recommendations, there still will be an immense opportunity to decrease waste and associated costs without sacrificing quality.” Additional opportunities could be seen for other infused medications when the dose is based on body weight, he added.

The company is creating an outreach program to monitor prior authorizations proactively, educate physicians and ask whether they’re willing to engage in dose rounding for these drugs when clinically appropriate, Dr. Leo said.

Palliative Care a Target

Dose rounding also could yield significant savings for metastatic cancer patients where cure is not the goal, according to a similar study by M. Sitki Copur, MD, FACP, the medical director of oncology for Saint Francis Cancer Treatment Center, in Grand Island, Neb.

The study, presented at the American Society of Clinical Oncology’s 2016 annual meeting (abstract 6616) and in press at the *Journal of Oncology Pharmacy Practice*, reviewed records from metastatic cancer patients treated with eight monoclonal antibodies at the community hospital from October 2014 through October 2015.

Dr. Copur and his colleagues identified 728 total doses of monoclonal antibodies that were suitable for dose down-rounding, including 323 doses of bevacizumab, 232 doses of rituximab, 46 doses of cetuximab (Erbix, Lilly), 42 doses of ramucirumab (Cyramza, Lilly), 40 doses of panitumumab (Vectibix, Amgen) and 36 doses of nivolumab (Opdivo, Bristol-Myers Squibb).

At 5% dose down-rounding or lower, 255 of the 728 doses (35%) qualified, for a potential annual cost savings of more than \$220,000. At 10% dose down-rounding or lower, 526 of the 728 doses (72%) qualified, for a potential annual cost savings of more than \$454,000. The overall average potential cost savings per qualifying dose reduction was around \$865.

“Someone could say, ‘Well, you’re undertreating the patients,’ but the truth is you are not,” Dr. Copur said in a telephone interview. It is a common practice in oncology to not alter the administered dose of chemotherapy drugs from cycle to cycle unless there is a greater than 5% to 10% change in actual body weight, he explained, and another common practice is a general dose rounding at 5% to 10% in the use of cytotoxic chemotherapy agents. Therefore, “a practical dose down-rounding approach as we suggest may allow significant cost savings in the [palliative care] metastatic cancer setting.”

However, current guidelines and practices on vial size and leftover drug use vary, Dr. Copur acknowledged. The FDA requires drug manufacturers to balance vial contents so leftover drug is minimized while also providing enough drug so more than one vial rarely is needed for a single dose. The Centers for Medicare & Medicaid Services encourages vial sharing, whereas the CDC considers the practice to be unsafe.

Still, Dr. Copur said, with monoclonal antibodies, “every milligram adds up to hundreds of thousands of dollars. They’re very expensive and have short half-lives and single-time use limits, making it more meaningful to do dose rounding.”

Electronic medical records can include an application that automatically calculates the 5% to 10% reduction to save drug wastage, he said.

—Karen Blum

The sources reported no relevant financial relationships.