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Readers Request Information About Extravasation Treatment

The *Clinical Journal of Oncology Nursing* has received inquiries about the costs associated with the use of Totect™ (TopoTarget USA, Inc.) for extravasation as well as clarification about the differences between Totect and Zinecard® (Pfizer Inc.) in reference to the article titled, "Totect™: A New Agent for Treating Anthracycline Extravasation" (Vol. 11, pp. 387-395).

The Author Responds

At the time the article was published (June 2007), Totect pricing was not yet available. The replacement-kit policy (TopoTarget replaces expired kits at no cost if unused) was announced in September 2007, after the article was in print.

Although scientific articles rarely include drug pricing, healthcare providers generally need to be aware of costs. The price of a Totect extravasation kit may seem high, but the costs associated with extravasation treatment (e.g., surgical procedures, skin grafting, physical therapy) are much higher. Patients with extravasation injuries also often need to stop chemotherapy while their injuries heal; delaying cancer treatment may adversely impact patients' treatment outcome—it is difficult to put a price tag on that. There are other costs as well, such as the cost of litigation that often ensues, the cost to an institution's reputation, and intangible costs to the patient (e.g., disfigurement, functional impairment, inability to work).

What seems like a high Totect kit price may actually be a significant cost savings.

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Disclosure: Following publication of my article on Totect, I have served as a consultant to TopoTarget USA, manufacturer of Totect.

TopoTarget Responds

Thank you for giving TopoTarget the opportunity to respond to your readers' comments.

Totect and Zinecard have several distinct differences. First, Totect is the first and only anthracycline extravasation treatment approved by the U.S. Food and Drug Administration (FDA). Zinecard and generic dexrazoxane are not FDA-approved for this indication. In addition, the FDA designated Totect as an orphan drug (i.e., a drug developed for a patient population of 200,000 or less). Anthracycline extravasations are extremely limited, with about 500-1,000 occurring per year in the United States (0.001%-1% of all anthracycline infusions). The population is so small that most companies would not have invested in the clinical studies required to show efficacy and safety to gain FDA approval. The FDA encouraged the product's development by providing seven years of protection for the indication.

The dosing and administration schedule of Totect are very different from Zinecard's. Totect also is packaged as a complete three-day treatment kit for single-patient use. The wholesale acquisition cost of one vial of generic dexrazoxane 250 mg is \$205.23; therefore, 20 individual vials (the number of vials needed to equal the ten 500 mg vials of

Totect in the Totect treatment kit) would cost \$4,104. The cost of the Totect kit is \$14,750 and includes a replacement-kit policy (i.e., original kits are replaced at no charge if they are unused and expire). Our replacement-kit policy needs to be considered when comparing costs.

Drug pricing takes many factors into consideration, including research and drug development, clinical trial costs (two multicenter clinical trials of biopsy-confirmed anthracycline extravasations treated with Totect were conducted and a third is almost complete with the data to be reported in 2008), and product support (e.g., reimbursement assistance). TopoTarget is committed to educating healthcare providers about extravasation prevention, detection, and management and offers live, print, and online educational programs. Patient information is available online at www.totect.com.

TopoTarget has a U.S. patent for the use of Totect for extravasation treatment, and purchasers of Totect receive a license to use Totect. Per U.S. patent law, substitution of any other form of dexrazoxane (including Zinecard) for Totect anthracycline extravasation treatment constitutes patent infringement. Why would anyone want to use a non-FDA approved product to treat anthracycline extravasations when an FDA-approved product is available? And most importantly, why would anyone want anything less than high-quality care for their patients?

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