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IN THIS ISSUE

In Brief: Dinutuximab (*Unituxin*) for High-Risk Neuroblastomaonline only

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IN BRIEF

Dinutuximab (*Unituxin*) for High-Risk Neuroblastoma

The FDA has approved use of dinutuximab (*Unituxin* [yoo ni tux' in] – United Therapeutics) in combination with interleukin-2 (IL-2), granulocyte-macrophage colony-stimulating factor (GM-CSF), and isotretinoin for treatment of children with high-risk neuroblastoma who previously responded to first-line therapies. Dinutuximab is a monoclonal antibody that binds to GD2, a glycolipid that is overexpressed on the surface of neuroblastoma cells.¹

Dinutuximab received a priority review and orphan drug designation. Approval was based on the results of an open-label trial in 226 patients with high-risk neuroblastoma that had at least a partial response to induction chemotherapy, autologous stem cell transplantation, and radiation. Patients were randomized to receive a combination of dinutuximab, GM-CSF, IL-2, and isotretinoin, or isotretinoin alone. At 2 years, the event-free survival rate, the primary endpoint, was 66% with the dinutuximab regimen and 46% with isotretinoin alone ($p < 0.01$). The overall survival rate was 86% with the dinutuximab regimen compared to 75% with isotretinoin alone ($p < 0.02$).²

The recommended dose of dinutuximab is 17.5 mg/m² daily infused IV over 10-20 hours for 4 consecutive days for up to 5 cycles. Dinutuximab can cause life-threatening infusion reactions, severe pain requiring treatment with IV opioids, peripheral neuropathy, capillary leak syndrome, visual disturbances, hemolytic-uremic syndrome, and other serious adverse effects. The cost for one 17.5 mg single-use vial is \$7,500.³ ■

1. S Dhillon. Dinutuximab: first global approach. *Drugs* 2015; 75: 923.
2. AL Yu et al. Anti-GD2 antibody with GM-CSF, interleukin-2, and isotretinoin for neuroblastoma. *N Engl J Med* 2010; 363:1324.
3. Approximate WAC. WAC = wholesaler acquisition cost, or manufacturer's published price to wholesalers; WAC represents published catalogue or list prices and may not represent an actual transactional price. Source: AnalySource® Monthly. March 5, 2016. Reprinted with permission by First Databank, Inc. All rights reserved. ©2016. www.fdbhealth.com/policies/drug-pricing-policy.

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