Darzalex Approved for Multiple Myeloma

On Nov. 16, 2015, the U.S. Food and Drug Administration (FDA) approved Darzalex® (daratumumab – Janssen Biotech) injection for intravenous (IV) infusion. It is a monoclonal antibody indicated for treating patients who have had three or more previous treatments for multiple myeloma, including a proteasome inhibitor, such as Kyprolis® (carfilzomib) and an immunomodulator, such as Revlimid® (lenalidomide); or whose multiple myeloma is resistant to both a proteasome inhibitor and an immunomodulatory agent. The recommended dose is 16mg/kg of body weight given by IV infusion once a week for the first eight weeks of treatment, then once every two weeks up to week 24, and then once every four weeks until it is no longer effective. Janssen Biotech plans on launching Darzalex within two weeks. Complete prescribing information is available at: www.darzalex.com

At a Glance

- **Brand (Generic) Drug:** Darzalex® (daratumumab)
- **Manufacturer:** Janssen Biotech
- **Date Approved:** Nov. 16, 2015
- **Indications:** To treat patients with multiple myeloma who have received at least three prior lines of therapy, including a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD), or who are double-refractory to a PI and IMiD.
- **Launch Date:** Within two weeks
- **Estimated Annual Cost:** Based on the average wholesale acquisition cost, Darzalex will cost approximately $134,500 for the first year of treatment and $76,000 per year thereafter.
- **Dosage Forms Available:** 100mg/5mL and 400mg/20mL solution in single-dose vials
- **Specialty Status:** Darzalex will be added to Express Scripts’ specialty drug list.
- Multiple myeloma is a cancer of bone marrow cells that will affect about 27,000 individuals and claim around 11,000 lives in the U.S., this year.
- Darzalex is the first CD38 monoclonal antibody to be approved by FDA. It works by sticking to CD38 glycoproteins that accumulate on the surfaces of multiple myeloma and other cancer cells. Darzalex causes cancer cells to break up while also promoting immune responses.
- Darzalex was approved several months ahead of schedule under FDA’s accelerated approval, breakthrough, orphan drug and priority review programs.
- Bristol-Myers Squibb and AbbVie’s Empliciti (elotuzumab) is another infused biologic drug that is expected to be approved by Mar. 1, 2016, for the treatment of multiple myeloma as combination therapy in patients who have received one or more prior therapies.