

Review, November 10, 2011 - Hemacord

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Office Director

Office of Cellular, Tissue, and Gene Therapy

Center for Biologics Evaluation and Research

Food and Drug Administration

Office Director Review

Based on information from the docket and other sources cited in the reviews, HEMACORD will be licensed for the following indication:

Hematopoietic progenitor cells, cord blood is an allogeneic cord blood hematopoietic progenitor cell therapy indicated for use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment. The risk benefit assessment for an individual patient depends on the patient characteristics, including disease, stage, risk factors, and specific manifestations of the disease, on characteristics of the graft, and on other available treatments or types of hematopoietic progenitor cells.

I have considered the reviews which evaluated data from the docket and other sources, as well as the discussion at the Advisory Committee meeting of the CTGTAC held on 9/22/2011 to discuss this application. Although hematopoietic recovery, following transplantation with HPC-C, varies by disease and other clinical factors, as well as factors associated with the graft, the data demonstrate that cord blood can be used as a source of hematopoietic progenitor cells for transplantation. Data in a variety of disease indications demonstrates that this hematopoietic recovery is associated with benefit to selected patients. For these reasons, the above indication is appropriate. However, because of the risks including graft failure, GVHD, engraftment syndrome, and infusion reactions, careful consideration of patient and graft characteristics, and other available treatments, should be incorporated in selection of this treatment option for an individual patient, and this information will be incorporated into the label.

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