EVOMELA
(melphalan)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Evomela (melphalan) is an alkylating agent for intravenous injection for conditioning treatment prior to hematopoietic stem cell transplant (HSCT) for patients with multiple myeloma and to treat multiple myeloma. Evomela inhibits DNA replication and transcription causing cytotoxicity in multiple myeloma. Evomela is a new propylene glycol (PG)-free IV formulation of melphalan. This new formulation increases stability of melphalan (1).

Regulatory Status
FDA-approved indication: Evomela is an alkylating drug indicated for: (1)

1. Use as a high-dose conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation in patients with multiple myeloma
2. The palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate

Evomela has a boxed warning citing the risk of severe bone marrow suppression, hypersensitivity, and leukemogenicity. Severe bone marrow suppression with resulting infection or bleeding may occur. Controlled trials comparing intravenous (IV) melphalan to oral melphalan have shown more myelosuppression with the IV formulation. Monitor complete blood counts. Hypersensitivity reactions, including anaphylaxis, have occurred in approximately 2% of patients who received the IV formulation of melphalan. Discontinue treatment with Evomela for serious hypersensitivity reactions. Melphalan produces chromosomal aberrations in vitro and in vivo. Evomela should be considered potentially leukemogenic in humans (1).

The use of Evomela is contraindicated in patients with a history of serious allergic reaction to melphalan (1).

Safety and effectiveness in pediatric patients have not been established (1).

Summary
Evomela (melphalan) is an alkylating agent for intravenous injection for conditioning treatment prior to hematopoietic stem cell transplant (HSCT) for patients with multiple myeloma and to treat multiple myeloma. Melphalan inhibits DNA replication and transcription causing cytotoxicity in

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multiple myeloma. Evomela label includes a boxed warning citing the risk of severe bone marrow suppression, hypersensitivity, and leukemogenicity. The safety and effectiveness in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Evomela while maintaining optimal therapeutic outcomes.

References