
5.21.78

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Antineoplastic Agents	Original Policy Date:	April 22, 2016
Subject:	Evomela	Page:	1 of 4

Last Review Date: March 12, 2021

Evomela

Description

Evomela (melphalan)

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 for palliative treatment of patients with 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 indications: 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).

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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).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Evomela may be considered **medically necessary** in patients 18 years of age or older with multiple myeloma and if the conditions indicated below are met.

Evomela may be considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Multiple myeloma – conditioning treatment
 - a. Used prior to hematopoietic progenitor (stem) cell transplantation
2. Multiple myeloma – palliative treatment

AND the following:

1. Inadequate treatment response, intolerance, or contraindication to generic injectable melphalan
2. If patient or their partner are of child bearing age, the patient has been or will be instructed to practice effective contraception during therapy and after treatment

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Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Multiple myeloma – palliative treatment

AND the following:

1. **NO** disease progression or unacceptable toxicity

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 3 months

Prior - Approval *Renewal* Limits

Multiple myeloma – palliative treatment only

Duration 6 months

Rationale

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 for palliative treatment of patients with multiple myeloma. Melphalan inhibits DNA replication and transcription causing cytotoxicity in 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).

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

References

1. Evomela [package insert]. East Windsor, NJ: Acrotech Biopharma LLC; August 2019.

Policy History

Date	Action
April 2016	Addition to PA
June 2016	Annual review
September 2016	Annual editorial review Removal of inadequate treatment response, intolerance, or contraindication to oral melphalan per SME
June 2017	Annual editorial review
June 2018	Annual editorial review and reference update
June 2019	Annual review
June 2020	Annual review and reference update
March 2021	Annual editorial review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.