Medical Policy:

Evomela® (melphalan)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.220	April 9, 2025	

Definitions

Melphalan is an alkylating agent of the bischloroethylamine type. Melphalan is a bifunctional alkylating agent and is cell cycle–phase nonspecific. Its cytotoxic action is primarily due to cross-linking of strands of DNA.

Length of Authorization

Multiple Myeloma-Conditioning Treatment: 30 days for 2 doses
Multiple Myeloma-Palliative Treatment: 6 months

Guideline

I. INITIAL APPROVAL CRITERIA

Coverage is provided in the following conditions:

1. **Multiple Myeloma-Conditioning Treatment**
   - A. Patient is 18 years of age or older; **AND**
   - B. Evomela is prescribed by, or in consultation with, an Oncologist or Hematologist; **AND**
   - C. Evomela is used as a high-dose conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation in patients with multiple myeloma.

2. **Multiple Myeloma-Palliative Treatment**
   A. Patient is 18 years of age or older; **AND**
   B. Evomela is prescribed by, or in consultation with, an Oncologist or Hematologist; **AND**
   C. Evomela is used for the palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate.

II. RENEWAL CRITERIA

Coverage can be renewed based upon the following criteria:

1. Patient continues to meet the criteria identified above; **AND**
2. There is evidence of response to therapy and stabilization of disease; **AND**
3. Absence of unacceptable toxicity from the drug

Limitations/Exclusions:

1. Member must be 18 years of age or older
2. Contraindicated in history of serious allergic reaction to melphalan
3. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

Dosing/Administration:

Indication	Dose
Conditioning Treatment	The recommended dose of Evomela for conditioning treatment is 100 mg/m^2/day administered over 30 minutes by intravenous infusion for 2 consecutive days (Day -3 and Day -2) prior to autologous stem cell transplantation (ASCT, Day 0). For patients who weigh more than 130% of their ideal body weight, body surface area should be calculated based on adjusted ideal body weight. Administer prophylactic antiemetics. No dose adjustment is necessary for conditional treatment.
Palliative Treatment	The recommended dose of Evomela for palliative treatment is 16 mg/m^2 administered as a single intravenous infusion over 15-20 minutes at 2-week intervals for 4 doses, then, after adequate recovery from toxicity, at 4Dweek intervals. Administer prophylactic anti-emetics. Dosage reduction of up to 50% should be considered in patients with renal impairment (BUN ≥30 mg/dL)

Applicable Procedure Codes

Code	Description
J9246	Injection, melphalan (evomela), 1 mg
J9249	Injection, melphalan (apotex), 1 mg

Applicable NDCs

Code	Description
68152-0109-00	Evomela Intravenous Powder for Solution: 50 mg
72893-0001-01	Evomela Intravenous Powder for Solution: 50 mg single dose vial

ICD-10 Diagnoses

Code	Description
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	04/09/2025	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	3/12/2024	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	7/03/2023	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	6/15/2022	Transferred policy to new template.
EmblemHealth & ConnectiCare	7/17/2020	Annual review

References

1. Product Information: EVOMELA intravenous injection, melphalan intravenous injection. Spectrum Pharmaceuticals, Inc. (per FDA), Irvine, CA, 2016.
2. Melphalan. IBM Micromedex® [database online]. Greenwood Village, CO. Truven Health Analytics. Available at: https://www.micromedexsolutions.com. Updated July 7, 2020. Accessed July 15, 2020.
3. Mikhael J, Ismaila N, Cheung MC, et al: Treatment of multiple myeloma: ASCO and CCO joint clinical practice guideline. J Clin Oncol 2019; 37(14):1228-1263.