

Medical Policy:

Evomela® (melphalan)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.220	March 12, 2024	

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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 antiemetics. 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

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	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.