Evomela (melphalan)

Humana

Pharmacy Coverage Policy

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Line of Business: Medicare, Commercial, Medicaid - Humana, Medicaid - Ohio
Policy Type: Prior Authorization

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Description

Evomela (melphalan) is an alkylating agent.

Evomela (melphalan) is indicated for use as a high-dose conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation in patients with multiple myeloma and for the palliative treatment of patients with multiple myeloma, for whom oral therapy is not appropriate.

Melphalan is available as Evomela in 50 mg sterile lyophilized powder in a single-dose vial.

Coverage Determination

Please note the following regarding medically accepted indications:

All reasonable efforts have been made to ensure consideration of medically accepted indications in this policy. Medically accepted indications are defined by CMS as those uses of a covered Part D drug that are approved under the federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. These compendia guide review of off-label and off-evidence prescribing and are

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subject to minimum evidence standards for each compendium. Currently, this review includes the following references when applicable and may be subject to change per CMS:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Truven Health Analytics Micromedex DrugDEX
- Elsevier/Gold Standard Clinical Pharmacology
- Wolters Kluwer Lexi-Drugs

Evomela (melphalan) will require prior authorization. This agent may be considered medically necessary when the following criteria are met:

Multiple Myeloma

- The member has a diagnosis of multiple myeloma **AND**
- The member will receive Evomela as:
  - High-dose conditioning treatment prior to stem cell transplant **OR**
  - Palliative treatment in members for whom oral therapy is not appropriate

Systemic Light Chain Amyloidosis

- The member has a diagnosis of systemic light chain amyloidosis
- The member will receive Evomela as:
  - Primary treatment **AND**
  - High-dose single-agent therapy with stem cell transplant

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Evomela (melphalan) will be approved in 6 month durations or as determined through clinical review.

Coverage Limitations

Evomela (melphalan) therapy is not considered medically necessary for members with the following concomitant conditions:

- Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

Background

This is a prior authorization policy about Evomela (melphalan).

Warning and Precautions:

- 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 hematologic laboratory parameters.
- 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.
- Gastrointestinal toxicity: nausea, vomiting, diarrhea or oral mucositis may occur; provide supportive care using antiemetic and antidiarrheal medications if needed.
- Embryo-fetal toxicity: Can cause fetal harm. Advise of potential risk to fetus and to avoid pregnancy.
- Infertility: Melphalan may cause ovarian function suppression or testicular suppression.

Dose Modification for Renal Impairment

- Conditioning Treatment: No dose adjustment is necessary
- Palliative Treatment: Dosage reduction of up to 50% should be considered in patients with renal impairment (BUN ≥30 mg/dL)

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Provider Claims Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Evomela; melphalan; multiple myeloma; pharmacy; intravenous

References

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Evomela [package insert]. Irvine, CA: Spectrum Pharmaceuticals, Inc; August 2021.

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Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.

Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically.

NCCN Drug and Biologics Compendium. Fort Washington, PA: National Comprehensive Cancer Network (NCCN); Updated periodically.

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