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Coverage Policy Number **IP0458**

Bleomycin Sulfate

Table of Contents

Related Coverage Resources

Oncology Medications – (CP1403)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for bleomycin sulfate (Bleomycin) for non-oncology indications.

The use of bleomycin sulfate for oncology indications are addressed in a separate coverage policy. Please refer to the related coverage policy link above (Oncology Medications).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Bleomycin sulfate (Bleomycin®) is considered medically necessary when the following are met:

1. **Recalcitrant verruca vulgaris.** Individual meets the following criteria:

A. Used for the treatment of symptomatic recalcitrant verruca vulgaris (unresponsive to all other treatments)

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Bleomycin sulfate (Bleomycin) is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other non-oncology use is considered experimental, investigational or unproven.

Coding / Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J9040	Injection, bleomycin sulfate, 15 units

Background

OVERVIEW

Bleomycin for Injection, USP should be considered a palliative treatment. It has been shown to be useful in the management of the following neoplasms either as a single agent or in proven combinations with other approved chemotherapeutic agents[1]:

Squamous Cell Carcinoma: Head and neck (including mouth, tongue, tonsil, nasopharynx, oropharynx, sinus, palate, lip, buccal mucosa, gingivae, epiglottis, skin, larynx), penis, cervix, and vulva. The response to Bleomycin for Injection is poorer in patients with previously irradiated head and neck cancer.

Lymphomas: Hodgkin's disease, non-Hodgkin's lymphoma.

Testicular Carcinoma: Embryonal cell, choriocarcinoma, and teratocarcinoma.
Bleomycin for Injection, USP has also been shown to be useful in the management of:

Malignant Pleural Effusion: Bleomycin for Injection is effective as a sclerosing agent for the treatment of malignant pleural effusion and prevention of recurrent pleural effusions

Verruca Vulgaris: The use of bleomycin for cutaneous warts has been evaluated in numerous placebo-controlled randomized trials with cure rates that were between 16% and 94% of warts and disparate conclusions on efficacy[2]. Some of the trials found efficacy of intralesional bleomycin, however, others found no benefit[2]. In two randomized trials, bleomycin was more effective than cryotherapy[3,4]

Bleomycin is either injected directly into warts or applied to the surface of the wart followed by pricking the surface of the wart multiple times to allow for penetration of the drug (so-called "scarification" technique). Often, bleomycin is given as a 1 mg/mL solution, although lower-strength preparations (0.5 mg/mL or 0.1 mg/mL) also may be effective. Bleomycin treatment induces significant pain, and prior or simultaneous injection of local anesthesia is recommended.

An “Authorized Generic Drug” means any drug sold, licensed, or marketed under a new drug application (NDA) approved by the Food and Drug Administration (FDA) under section 505(c) of the Federal Food, Drug and Cosmetic Act (FFDCA) that is marketed, sold or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the brand name drug (the “Reference Brand Drug”).

References

1. Bleomycin sulfate [prescribing information]. Lake Zurich, IL. December 31, 2019.
2. Topical treatments for cutaneous warts. Kwok CS, et al. Cochrane Database Syst Rev. 2012
3. Compared therapeutic efficacy between intralesional bleomycin and cryotherapy for common warts: a randomized clinical trial. Adalatkhah H, et al. Dermatol Online J. 2007;13(3):4
4. Intralesional bleomycin in the treatment of cutaneous warts: a randomized clinical trial comparing it with cryotherapy. Dhar SB, et al. Indian J Dermatol Venereol Leprol. 2009 May-Jun;75(3):262-7.