

STANDARD MEDICARE PART B MANAGEMENT

ZEVALIN (ibritumomab tiuxetan)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- A. **Relapsed or Refractory, Low-grade or Follicular NHL**
Zevalin is indicated for the treatment of adult patients with relapsed or refractory, low-grade or follicular B-cell non-Hodgkin's lymphoma (NHL).
- B. **Previously Untreated Follicular NHL**
Zevalin is indicated for the treatment of previously untreated follicular NHL in adult patients who achieve a partial or complete response to first-line chemotherapy.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

- A. **Relapsed or Refractory, Low-grade or Follicular Non-Hodgkin's Lymphoma (NHL)**
Authorization of 12 months may be granted for treatment of relapsed or refractory, low-grade or follicular B-cell non-Hodgkin's lymphoma (NHL).
- B. **Previously Untreated Follicular NHL**
Authorization of 12 months may be granted for previously untreated follicular NHL in members who have achieved a partial or complete response to first-line chemotherapy.

III. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Zevalin.
2. The available compendium
 - a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
 - b. Micromedex DrugDex
 - c. American Hospital Formulary Service- Drug Information (AHFS-DI)
 - d. Lexi-Drugs
 - e. Clinical Pharmacology

Reference number(s)
5755-A

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Zevalin are covered.

IV. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

V. REFERENCES

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