Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 15.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Zevalin (Ibritumomab tiuxetan (IDEC Y2B8))

I. Policy:
Zevalin (Ibritumomab tiuxetan (IDEC Y2B8))

II. Purpose/Objective:
To provide a policy of coverage regarding Zevalin (Ibritumomab tiuxetan (IDEC Y2B8))

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
ZevalinTM (ibritumomab tiuxetan) is the immunoconjugate resulting from a stable thiourea covalent bond between the monoclonal antibody ibritumomab and the linker-chelator tiuxetan. Zevalin binds specifically to the CD20 antigen (human B-lymphocyte-restricted differentiation antigen, Bp35) and prevents shedding from the cell surface and internalization upon antibody binding.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Zevalin (Ibritumomab tiuxetan (IDEC Y2B8)) will be considered medically necessary for all lines of business when all of the following criteria are met:

1 Zevalin® is approved for the treatment of patients with relapsed or refractory, low-grade or follicular B-cell non-Hodgkin's lymphoma (NHL) including patients with Rituxan (rituximab) refractory follicular non-Hodgkin's lymphoma, when **ALL of the following criteria are met:**
- Zevalin® must be requested by an Oncologist/Hematologist.
- Physician provided documentation of use in combination with rituximab 250 mg/m^2 given on days 1 and 7, 8, or 9 of therapy
- Physician provided documentation of a neutrophil count $\geq$1500 cells/mm^3
- Physician provided documentation of a platelet count of $\geq$100,000 cells/mm^3
- No evidence of ≥ 25% lymphoma marrow involvement
- No evidence of hypocellular bone marrow (15% or less cellularity or marked reduction in bone marrow precursors)
- No history of failed stem cell collection
- No history of a prior bone marrow transplantation

2 Zevalin® is approved for the treatment of patients with previously untreated follicular NHL following a response to initial anticancer therapy when **ALL of the following criteria are met:**
- Zevalin® must be requested by an oncologist/hematologist
- Physician provided documentation of use in combination with rituximab 250 mg/m^2 given on days 1 and 7, 8, or 9 of therapy
- Physician provided documentation of a neutrophil count ≥1500 cells/mm^3
- Physician provided documentation of a platelet count of $\geq$100,000 cells/mm^3
- No evidence of ≥ 25% lymphoma marrow involvement
- No evidence of hypocellular bone marrow (15% or less cellularity or marked reduction in bone marrow precursors)
- No history of failed stem cell collection
- No prior external beam radiation or myeloablative therapy
- Medical record documentation that therapy is being initiated at least 6 weeks but no more than 12 weeks following last dose of first line chemotherapy

AUTHORIZATION DURATION:
Zevalin is limited to one course of treatment. Authorization will be given for one infusion. Additional administration of the drug will require another prior authorization

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Zevalin [prescribing information]. East Windsor, NJ: Acrotech Biopharma LLC; April 2023.
2. Wiseman, GA, White CA, Stabin M, et al. Phase I/II 90Y-Zevalin (yttrium-90 ibritumomab tiuxetan, IDEC-Y2B8) radioimmunotherapy dosimetry results in relapsed or refractory non-Hodgkin's lymphoma. European Journal of Nuclear MEdicine; 2000 June; 27:766-77 [cited 2023 Dec 28]. Available from: https://link.springer.com/article/10.1007/s002590000276

This policy will be revised as necessary and reviewed no less than annually.

Devised: 1/29/03

Revised: 5/04 (prior auth requirement); 06/06 HGSA; 2/12 (criteria); 12/12 added indication; 08/14, 09/26/14, 12/21/21 (removal of “distinct therapeutic features” and “caution” informational sections), 12/19/22 (LOB carve out, Medicaid PARP statement), 1/23/23 (r/r low-grade or follicular clarification per DHS), 12/31/23 (references added), 1/15/24 (Medicaid business segment)

Reviewed: 5/05, 7/07, 2/10, 3/11, 08/14, 09/26/14, 11/2/15, 9/20/16, 7/31/17, 7/10/18, 5/31/19, 2/1/20, 1/1/21

MA UM Committee approval: 12/31/23